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Under India's G20 Presidency of 2023 the New Delhi Leaders' Declaration 'recognising the potential role of evidence-based Traditional and Complementary Medicine in health, and take note of international efforts in this direction, including WHO's global and collaborating centres, and clinical trial registries', augurs well for traditional medicines and the international policy outreach envisaged for these systems. As a group of countries with more than 60 per cent of global population endorses the relevance of traditional medicine, the acceptance of these systems as a part of universal healthcare programmes is projected to increase. However, the endorsement is not without caveats. The Declaration mentions 'evidence based' traditional medicines, thereby emphasising the need for more clinical research and clinical trials conforming to existing standards and protocols for biopharmaceuticals. Stability, standardisation and quality control of medicinal plants also become important issues as these are closely aligned with drug development of phytopharmaceuticals. In this backdrop, the current issue covers several important dimensions of economy, political economy and anthropology of traditional medicine systems as they navigate multilateral groups and institutions in the quest for globally sustainable health solutions.

T.C. James in his article on opportunities and challenges for G20 economies in traditional medicine explores the relationship between T&CM and the economic development of G20 countries and argues for exploiting its economic potential for national and global economic development. Rabi Narayan Acharya maps the status of Ayurveda and its prospects in G20 countries. Aside from countries with evolved institutionalisation and integration of traditional medicine systems such as India and China, several others with strong oral traditions have taken initiatives in regulatory streamlining of their respective national systems. One such example is South Africa. Rajendran Govendar attempts an anthropological exploration of socio-cultural, economic and health dimensions of traditional healing practices in South Africa. With insights drawn from historical narratives, cultural practices and legislative developments he sheds light on the symbiotic relationship between tradition and modernity in the realm of healthcare in South Africa. The nature of traditional medicine practices, with each system indigenous to a country or region conforming to a diverse set of protocols makes global integration a challenge. Nandini Kumar emphasises that clinical research is an important requirement for evidence based harmonisation of traditional medicines. As such all components like ethical guidelines, regulations, design of the research,

procurement and standardization of test formulations, conduct of research and publication of the outcomes are important. Despite the desirability of uniformity of standards it must be acknowledged that a significant challenge lies with raw materials of herbal medicines, i.e. medicinal plants. The chemical composition of herbal preparations can vary significantly depending on numerous factors such as the region where plants were grown, the season of harvest, and even between individual plants within the same species. The management of medicinal plant genetic resources faces debate on another front. Today the issue of access and benefit sharing has moved beyond the legal obligations established by United Nations Convention on Biological Diversity. Namrata Pathak reviews the book based on this issue, i.e. Access and Benefits of Genetic Resources, Information and Traditional Knowledge edited by Charles Lawson, Michelle Rourke and Fran Humpfries.

I hope scholars and practitioners find this issue useful in understanding the changing nature of debates on traditional medicines as these systems aspire for global outreach.

Sachin Cahturvedi

Traditional Medicine and Economic Development: Opportunities and Challenges for G20 Economies

Foolish the doctor who despises the knowledge acquired by the ancients.

-- Hippocrates

T C James*

T C James

Abstract : TM with its prevalence in almost all countries and with growing popularity has great economic potential. This opens a great new sector for cooperation and economic development in G20 countries. There are certainly many challenges such as concerns about safety and efficacy and doubts about the scientific validity of the principles of TM. From the market perceptive, regulations and standardization as well as certainty of product quality are quite important. With appropriate policy and strategy interventions by the governments definitely the G20 economies can leverage TM for economic development. It augurs well that the Delhi Declaration (2023) of the G20 countries has recognised "the potential role of evidence-based Traditional and Complementary Medicine in health, and take[n] note of international efforts in this direction, including WHO's global and collaborating centres, and clinical trial registries."[1] In this background, the article analyses and recommends a framework for promoting the economic potential of traditional medicine.

Introduction

Traditional medicine (TM) has been there from time immemorial, but in recent years it has drawn considerable attention for various reasons, including perceptions such as more accessibility and affordability than modern medicine and the increased aversion of

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many to chemical drugs. Around 80 per cent of people in about 170 countries is using some form of TM[2]. Dr Tedros Adhanom Ghebreyesus, Director-General of World Health Organisation (WHO) says that "for many millions of people around the world, traditional medicine is the first port of call to treat many diseases." [3] The WHO has been actively promoting TM and has established a Global Centre for TM at Jamnagar, Gujarat, India. WHO also organised its first-ever Traditional Medicine Global Summit in Gandhi Nagar, Gujarat, India in August 2023. It was attended by delegates from 88 countries including health ministers from G20 and other countries, scientists, practitioners of TM, health workers, TM pharma and members of civil society[4]. TM is not homogenous like modern medicine. A recent publication discusses the following TMs around the world: Chinese, Indian, Japanese, European, African, Yoruba, Persian, Arabic & Islamic, Mexican and Mediterranean. In addition, the book lists the following other TMs in an annexure: Australian, Brazilian, Caribbean, Ethiopian, Greek Classic, Jamaican, Jordanian, Korean, Malay, Russian, Thai, Tibetan, Aboriginal, Burmese, Lau, South African, Sri Lankan, Nepali, Oriental and Vietnamese (Sadik *et al*. 2022). In fact, TM is in almost every country most originated indigenously. This diversity itself reflects its acceptability among diverse groups and the potentiality of TM economy.

G20 countries like China and India have robust TM systems of their own with hundreds of thousands of practitioners and significant number of hospitals, dispensaries and large TM pharmaceutical industry. A recent study has estimated the size of Indian TM industry as USD 25 million (RIS 2021). It is a major economic sector and plays a significant role in the economic development of many G20 countries. As per a market research organization report, the herbal medicine market, a segment of TM market, was valued at USD 117.13 billion in 2021 and is projected to reach USD 532.05 billion by 2030, growing at a CAGR of 18.3 per cent from 2023 to 2030.[5] According to Fortune Business Insights, the global herbal medicine market size was USD 151.91 billion in 2021 and the market is forecast to grow from USD 165.66 billion in 2022 to USD 347.50 billion by 2029, exhibiting a CAGR of 11.16 per cent.[6] Another group has estimated the global market for herbal medicine around USD 180 billion in 2020 and growing at a CAGR of around 11 per cent.[7] While there are variations in the estimates of the size of TM industry, generally all project a rosy picture. It is, therefore, an important sector for economic development. This paper will explore the relationship between traditional & complementary medicine (T&CM) and the economic development of G20 countries. The G20, until the New Delhi summit, had represented 66 per cent of the world's population, 85 per cent of GDP, and 75 per cent of international trade.

Traditional Medicine and Economic Opportunities

TM has significant economic potential which can be effectively employed for national and global economic development. All stages of TM production, distribution and service are economic activities. This includes collection from the wild and cultivation of medicinal and aromatic plants (MAPs) which form the principal raw materials of TM. Both the activities are labour intensive and have huge employment potential (Dangwal 2017). Establishing a TM practice is not very resource-intensive. Indigenous people

mostly rely on TM and they account for six per cent of the world population, according to the World Bank[8] (World Bank 2015).

MAPs, TM products and herbal remedies have a global market. Countries with well-established TM systems are in a better position to export herbal products, medicinal plants, and traditional remedies to other countries, compared to others. Such exports consequently promote international trade, contributes to foreign exchange earnings, and stimulates economic growth. The TM market is estimated to reach USD 115 billion by the end of 2023 at a CAGR of 7.2 per cent during 2017-2023.[9] The global market for herbal products and medicinal plants was estimated at USD 60 billion in 2020[10]. The international trade of MAPs and their products are expected to reach USD 5 trillion by 2050 (Zahra *et al*. 2020).

As per the preliminary findings from the WHO Global Survey on Traditional Medicine 2023 shared at the Global Summit 2023, around 100 countries have Traditional, Complementary and Integrative Medicine (TC&IM) related national policies and strategies. That means there is a universal appeal for TM and has fair market prospects. In many WHO Member States, TC&IM treatments are part of the essential medicine lists, essential health service packages, and are covered by national health insurance schemes. A large majority of people seek TC&IM interventions for treatment, prevention and management of noncommunicable diseases, palliative care and rehabilitation.[11]

A sector that has a predominance of TM is that of wellness tourism. TM practices often attract tourists seeking holistic healing, wellness, and cultural experiences. Countries or regions with well-established TM systems can leverage this demand to develop wellness tourism. The medical tourism boosts the local economy also through tourism-related businesses such as hotels, spas, restaurants, and souvenir shops.

Examination of economic salience of TM cannot ignore the Intellectual Property (IP) aspects because IP Rights (IPRs) enable commercialisation. TM systems embody a wealth of indigenous knowledge and traditional practices. In order to get patent protection the TM innovation has to satisfy the criteria of novelty, inventiveness and industrial application or utility. While utility criterion can easily be fulfilled, the other two criteria pose major problems. An Inter-Governmental Committee (IGC) of the World Intellectual Property Organisation (WIPO) has been examining issues relating to IP protection for Traditional Knowledge (TK), Traditional Cultural Expressions (TCEs) and Genetic Resources (GRs) for more than two decades now and TM knowledge comes under TK. The discussions are still ongoing[12]. However, copyrights, geographical indications and trademarks, apart from trade secrets, can be employed for IPR protection. This allows communities and individuals to benefit financially from their TK and receive royalties or licensing fees when their traditional remedies or practices are used commercially.

Of late, there has been great stress on research and development (R&D) in TM. This creates opportunities for innovation, product development, and commercialization. The research efforts may focus on (a) scientific validation of a TM product, (b) identification of new uses of an existing formulation, (c) development of new dosages, and (d) new modern medicine drugs. Research institutions, pharmaceutical companies,

and biotechnology firms may conduct studies to validate the safety and efficacy of traditional remedies, identify active compounds, and develop new drugs or therapies based on TK. This can lead to the discovery of new treatments and the development of patentable products and processes. New advances will add to the economic prowess of TM.

Traditional Medicine in G20 countries

The following is a brief narration of TM status in G20 countries mostly based on the *WHO Global Report on Traditional and Complementary Medicine 2019* (WHO 2019). Other references are cited at the appropriate places.

Argentina: T&CM practices, mostly homeopathy, are used in Argentina, though on a limited scale. Among TM, only acupuncture is regulated. Argentina has exclusive national legislation on herbal medicines. Those categorized as prescription medicines are sold in pharmacies only whereas those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and also other outlets.

Australia: Natural therapy is an important and rapidly growing component of Australia's overall health system as of 2013, according to the Australian Medicine Society. More than 70 per cent Australians use some form of natural therapy as a regular part of their overall health care, with close to 2 million professional consultations conducted annually. A 2001 review estimated that approximately one billion Australian dollars are spent annually on T&CM (WHO 2001).

Brazil: TM practices, such as herbal medicine and indigenous healing systems, as well as homeopathy, are popular in Brazil. Since 1988, the government has recognised and included homeopathy in the National Health System (WHO 2001). The implementation of policies to regulate and promote TM has led to economic opportunities for local communities involved in the production and sale of herbal remedies.

Canada: TM products fall under the category of natural health products (NHPs) which also includes non-herbal products. There is a registration system for the NHPs and more than 56,000 products have been registered for sale. There is also a market surveillance system for checking the safety of medicines that also covers NHPs. Some government agencies provide health insurance under which indigenous TM services are covered. As per the WHO 2001 review, between 1996 and 1997, a total of 3.8 billion Canadian dollars were spent on TM&C based healthcare (WHO 2001).

China: Traditional Chinese Medicine (TCM) is a well-established and thriving industry in China. It includes various forms of Chinese herbal medicine, acupuncture, cupping, Tui Na and others. The country has made significant efforts to integrate TCM into its healthcare system and promote its economic development. China has been promoting and developing TCM since the second half of the 20th century. In the 1950s a Department of TCM was established in the Health Ministry followed by setting up of Academy and institutes for TCM. State Administration of TCM was established in 1986 and TCM hospitals were set up in each county. TCM hospitals, research institutes, and pharmaceutical companies contribute to job creation, export opportunities, and the growth of related industries. At the end of 2015, there were 3,966 TCM hospitals across the country, including 253 hospitals of ethnic minority medicine (such as Tibetan, Uyghur, Korean, Mongolian, and

Zhuang medicines) and 446 hospitals of integrated Chinese and Western medicine. There were 452,000 practitioners and assistant practitioners of TCM (including practitioners of ethnic minority medicine and integrated Chinese and Western medicine) and 42,528 TCM clinics, including 550 for ethnic minority medicine and 7,706 for integrated medicine.[13] These facilities handled 910 million visits in 2015 for TCM medical and health services nationwide and treated 26.915 million in-patients The total trade in TCM products within China in 2019 has been estimated as USD 6.174 billion and the export at USD 4.019[14]

As per official data, by the year 2013, 15.4 per cent of outpatients and 11.9 per cent of in-patients were getting TCM treatment nationally. By the same data 4.5 per cent of medical institutions and 7.5 per cent of registered physicians were from TCM. Of the total medical expenses in China, 6.36 per cent is on TCM[15]. After the Chinese economy opened up, TCM has become a high technology one and also a key driver of sustained development of the health industry. The total TCM product trade in 2019 was USD 6.174 billion (Xiang, et al. 2022). As per industry report on TCM by Emergenresearch, the market size of TCM is estimated as USD 18.80 billion in 2021.[16] Ibisworld estimates the market size of TCM manufacturing within China in 2023 at USD 50.9 billion.[17] As per Benzinga report, the global TCM market size was valued at USD 216.46 billion in 2022.[18]

There are many big TCM pharma companies in the global market like Sanjiu, Kangmei Pharmaceutical Co. Ltd., Tasly Pharmaceutical Group, TSUMURA, DEEJ, PIEN TZE HUANG, Guangzhou Pharma, YUNNAN BAIYAO, Beijing TongRenTang, Jiangsu Kanion Pharmaceutical Co. Ltd. and many others. There are 2,088 pharmaceutical companies certified by the Good Manufacturing Practice (GMP) in the country to produce Chinese patent medicines. A modern Chinese medicine industrial system based on medicinal material production, industry as the main body, and commerce as the link has been established. In 2015, the total output value of the Chinese medicine industry was Yuan 786.6 billion, accounting for 28.55 per cent of the pharmaceutical industry. In 2015, the export value of TCM reached USD 3.72 billion, showing a huge potential for overseas market development. According to a TCM *White Paper*, the TCM industry has gradually become a strategic industry with unique advantages and broad market prospects in the national economic and social development. (White Paper. 2016).

France[19]: France recognises and allows use of Complementary Medicines like homeopathy, acupuncture, and manual medicine (osteopathy and chiropractic). In addition to allopathic doctors, 36 per cent of whom have used T&CM in their practice, there are 50,000 non-allopathic practitioners who provide T&CM therapy (WHO 2001). There are traditional healers such as healers, magnetizers, bonesetters, fire burn healers, energy healers, and litho-therapists, among others. An estimated 75 per cent of population has had recourse to such medicines at least once. However, most people are reluctant to admit that they consult traditional healers for fear of appearing irrational, and traditional healers themselves are often discreet about their activity. Most traditional healers received the knowledge from within their family and practice at their homes (Herbreto *et al*).

Germany: The German drugs law includes provision for the registration of traditional herbal medicinal products. Herbal medicines are categorized as

prescription medicines, non-prescription medicines and herbal medicines. It is estimated that 60–79 per cent of the population in Germany uses some kind of TM. The 2001 WHO Review states that three-fourths of allopathic practitioners use complementary medicine. Further, there were between 10,000 and 13,000 practitioners of T&CM (WHO 2001).

India: India has a rich tradition of TM. Indian Systems of Medicine (ISMs) include Ayurveda, Yoga, Unani, Siddha, and Sowa Rigpa (Ayush). Besides, Homeopathy is also promoted in the country. There are also folk and tribal medicine practitioners. All medical practices other than modern medicine are regulated by the Ministry of Ayush.[20] The Indian government has implemented policies to promote TM and leverage its economic potential. Consequently it is a thriving sector. This includes the establishment of Ayush hospitals, research institutions, and the export of Ayush medicines and products. The dashboard of the Ministry of Ayush of the Government of India provides impressive figures of Ayush healthcare facilities:

ISMs are regulated like modern medicine under the Drugs and Cosmetics Act, 1940 of India, as per amendment in 1963. As on 1st January 2020, there are 712,132 registered Ayush doctors/practitioners.[23] Most of the TM manufacturing units (83 per cent) are GMP compliant (WHO. 2020). With good number of pharmaceutical firms in the sector, India's Ayush sector has great economic potential. There are many Ayush firms in India who are global players like Dabur India, Patanjali Ayurved, GlaxoSmithKline Pharmaceuticals, Marico, Hindustan Unilever and Lupin (RIS 2021). Some of these firms are also into production of modern pharmaceuticals, food supplements and cosmetics, underlying the fact that TM manufacturing is part of industrial activities. It attracted investment commitment of Rs. 90 billion (about USD 1.085 billion) in the Global Ayush Investment Summit 2022[24]. ISMs, particularly Ayurveda and Unani, are practised abroad also and Ayush products are important export items. They are being exported as MAPs, extracts, nutraceuticals, food supplements and medicaments, though major share is that of MAPs.

Table 1: Traditional Medicine (Ayush) healthcare facilities in India 2022

Item	Number
10-bedded Integrated hospital	17
30-bedded Integrated hospital	05
50-bedded Integrated hospital	115
Primary Healthcare Centre (PHC)	11,000
Community Healthcare Centre	8,000
District Healthcare Centre	900
Ayush hospital	12,000
Ayush dispensaries	36,068

Source: Ministry of Ayush dashboard.[21] [22]

Indonesia: Indonesian TM is known as Jamu (WHO 2020) and the country has a national policy on TM. T&CM is included in the 17 health services that are to be provided by every health facility in the country. As per the 2010 National Basic Health Survey, 40–59 per cent population uses indigenous TM. There is a registry for herbal medicines and 13,000 herbal medicines were registered under it by 2010. Acupuncture, Ayurveda and Chiropractic are used by people. Indonesia had more than 88,920 registered T&CM practitioners in 2019 (WHO 2020).

Italy: Herbal products are quite popular in Italy. Many of them are marketed as food or nutritional supplements or botanicals or cosmetics and some as herbal drugs. A health claim that recognizes a biological function, whether it be prevention, maintenance of homeostasis, or normalization of biological parameters is permitted to be associated with botanicals. There is a constantly increasing market (Biagi *et al* 2016). The Institute for Political, Social and Economic Studies (EURISPES) survey in 2010 finds that 18.5 per cent of the population uses T&CM. (Roberti *et al* 2011).

Japan: Japanese traditional herbal medicine is known as Kampo which has about 1500 years history and in recent years has seen a revival in medical practice. The quality of Kampo products is assured by a government authority and pharmaceutical companies. They have been included in the Japanese national health insurance drug list since 1971. Currently, 148 different formulations (mainly herbal extracts) can be prescribed under the insurance scheme. (Watanabe: 2011). In 1998, there were 260,724 registered practitioners of different T&CM therapies. In addition, around 72 per cent of allopathic practitioners also use Kampo (WHO 2001). The production of Kampo products based on crude drugs reached 192.7 billion yen in 2019[25]. There are 63 companies who are members of the Japan Kampo Manufacturers Association (JKMA).

Mexico: Mexico has a long history of TM, particularly among indigenous communities. The Mexican government has taken steps to recognize and protect traditional medicine knowledge and practices. TM tourism has also emerged as a growing sector, attracting visitors interested in traditional healing practices, herbal remedies, and alternative therapies. Mexico has the largest indigenous population in Latin America; they form 15 per cent of its population (World Bank 2015), a major constituency for TM.

Republic of Korea: South Korea has focused on the development of TM, known as "Hanbang," which includes traditional herbal medicine and acupuncture. The government has supported research, development, and commercialization of Hanbang products. Korea has 107 hospitals and 6,590 clinics in the T&CM sector, manned by 9,914 practitioners (WHO 2001). TM has also become a significant part of South Korea's medical tourism industry, attracting visitors seeking traditional healing practices. The 2020 Korean Medicine Utilization and Herbal Medicine Consumption Survey shows that the proportion of Koreans who used Korean medicine in their lifetime amounted for 69 per cent. (WHO 2020). The total sales value of the TM sector in 2021 amounted to around 10.9 trillion won[26].

Saudi Arabia: Indigenous TM is considered important in Saudi Arabia, with reported use by 40–59 per cent of the population. T&CM is used in every city and village. The popular therapies include acupuncture; herbal, nutritional, and health food products; and homeopathy. (WHO 2001).

South Africa: In South Africa, the national policy on T&CM was issued in 1996 as part of the national drug policy. While there is a national law and regulation on complementary medicine titled Chiropractors, Homeopaths and Allied Health Service Professions Second Amendment Act of 1982, there is no national law or regulation for TM. There are over 200,000 traditional healers (known as *inyangas, sangomas* and witch doctors) in the country. The T&CM industry is worth up to 2,300,000 South African rand per year (WHO 2001).

Turkey: Folk medicine is quite popular in Turkey (Ekrem *et al*. 2001). The practitioners are commonly known as herbalists. Turkey has a Department of T &CM established in 2012. Medicinal and aromatic plants occupy an important place in the economy of Turkey and there are many studies bringing out their salience[27]. Turkey has been promoting cultivation of improved varieties of MAP which reached production of 300,000 tons in approximately 100,000 hectares of land and exported about 50,000 tons which earned USD265 million in 2018. About 100 countries are in Turkey's export list of MAPs[28].

United Kingdom (UK): T&CM practices of acupuncture, Ayurveda, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, TCM and Unani medicine are used by the population in the UK. An estimated 20–39 per cent population uses herbal medicines. T&CM providers practise in public and private clinics and hospitals. Based on the information shared by the Medicines and Healthcare Products Regulatory Agency, as of 2012, there are an estimated 12,900 acupuncture providers, 3,200 herbal medicine providers and 2,800 TCM providers in the UK.

Russian Federation: TM is treated as nutrition products under Russian law[29]. The traditional Russian medicine is based on plants combined with the belief in one's ability to self-heal. It is quite popular. Many Russians display a certain mistrust towards modern allopathic treatments, preferring to rely on the remedies of their forefathers.[30] Ayurveda is also quite popular particularly since the Chernobyl nuclear plant disaster of 1989. In 1991 the first Russian professional medical association of practitioners of traditional and folk medicine (Russian Association of Traditional Medicine) was registered with the aim of training and registering practitioners of traditional and Oriental medicine. Besides, regular Ayurvedic treatments, there are about a thousand Spa-centres in Russia and roughly half of them offer services based on Ayurvedic techniques (Ragozin.2016).

United States of America (USA): Complementary & Alternative medicine has a good presence in the USA. Its rate of use has ranged between 32 to 54 per cent in 1997. The out-of-pocket expenditure on these therapies is estimated as USD 27 billion in that year. (WHO 2001). In the USA, the Dietary Supplement Health and Education Act of 1994 forms the national regulation on herbal medicines. There is no registration of herbal medicines and they are not included in the National Essential Medicine List.

European Union (EU) and African Union (AU): In addition to the above countries, the EU (27 countries) and now the AU (55 countries, 17.84 per cent of world population and 2.84 per cent of global GDP[31]) are members of the G20. TM has been quite popular and plays a prominent role in the public healthcare in Africa[32]. EU legislation on pharmaceutical products apply to traditional herbal medicines as well. It follows a registration procedure

that allows herbal medicinal products with a long tradition of medicinal use (at least 30 years, including 15 in the EU), which do not fulfil the "well established use" requirements for marketing authorisation, i.e. published scientific literature on recognised efficacy and safety[33].

The above status illustrates that TM has significant presence in most G20 countries, though in varying degrees. Recognizing the economic potential of TM most of them have implemented various strategies to promote its development. Few of them have robust TM industries. However, it will be necessary to conduct specific case studies for more detailed information and to explore the country experiences in-depth.

Traditional Medicine: Challenges and Barriers to Economic Development

Traditional Medicine faces several challenges in the current globalized economy such as "safety, standardization, ethics, culture clash, regulation, (and) overexploitation" (Sadiku *et al*. 2022). These are also the challenges and barriers faced by G20 economies in harnessing the economic potential of traditional medicine. Some of the key challenges from a G20 perspective are presented below.

Developing and implementing appropriate regulatory frameworks for TM products and practices is a major challenge since there are no universally accepted regulations. In the absence of universal regulations, TM products face challenges in meeting the registration and licensing requirements of different countries. TM products often have complex formulations and mode of actions that may bot align with conventional labelling requirements.

The WHO is currently pushing for evidence-based TM and in the First WHO Global Summit on TM, evidence-based Integrated Traditional and Complementary Medicine[34] received high focus (WHO 2023). However, conducting high-quality research and clinical trials on TM can present challenges. TM often relies on holistic approaches, personalized treatments, and complex interventions, which may not align well with the traditional randomized controlled trial (RCT) design, though *Kampo* medicine of Japan has taken to this path. Adequate funding, research infrastructure, and expertise are needed to generate rigorous scientific evidence. Without evidence as acceptable to modern science, TM will face regular criticisms from modern medicine practitioners and even general public health which will adversely affect its economic prospects (Thakur D & Reddy P. 2022).

Whatever be the stand on RCTs, it is absolutely essential to satisfy norms of safety and effectiveness for marketing medicinal products. Since they are critical for consumer protection. But, pharmacovigilance ensuring consistent quality and safety of TM products can be challenging due to variations in raw materials, manufacturing processes, and formulations. Developing and implementing standards for TM products that are accepted globally may take time, although national standards are available in countries like India[35]; for one, the reluctance of many health authorities to allow 'non-scientific' therapies and for another, the diversity of TMs itself. But quality control measures, GMPs, and product authentication techniques need to be established and enforced to build trust among consumers and healthcare professionals. The Ayush Marks (standard and premium) of India is a step in this direction.

Integrating TM into conventional healthcare systems, poses many challenges as TM often operates within different paradigms, diagnostic frameworks, and treatment philosophies, not only compared to modern medicine but also among them. Bridging gaps in knowledge, communication, and understanding between the two systems is difficult but is crucial for successful integration.

Protecting TK, traditional medicine practices, and associated IPRs is also not an easy task, as is evident from the ongoing more than two decades old discussions in the WIPO IGC. TM often originates from indigenous communities and local cultures, and the unauthorized use or misappropriation of TK can occur easily for sociological and economic reasons.

Linked with the above issue is that of conservation of biological resources since supply of medicinal plants, the principal raw material for TM, is dependent on that over exploitation of MAPs can be suicidal for TM industry. As suggested by a researcher, there is need to balance commercial values and conservation values in the matter of exploitation of biological resources, especially medicinal plants (Kumar 2006).

Addressing public perceptions and improving awareness and understanding of traditional medicine is essential to capture markets. Misconceptions, scepticism, and lack of awareness can hinder the acceptance and utilization of traditional medicine. Educating the public, healthcare professionals, and policymakers about the benefits, safety, and appropriate use of traditional medicine can help overcome these barriers and promote its economic potential. This, of course, requires scientific validation of most TM products, especially those to be taken as an internal medicine, in view of the concerns of healthcare authorities. Even the First WHO Global Summit on TM was also pushing for evidence-based TM only.

Gaining market access and commercializing TM products globally is easier said than done due to varying regulatory requirements, trade barriers, especially non-tariff trade barriers, and limited market acceptance. Exporting TM products may require compliance with different national regulatory frameworks and demonstrating safety and efficacy to international standards. Building distribution networks, establishing branding strategies, and competing with established pharmaceutical and healthcare industries can also pose challenges for traditional medicine enterprises.

Addressing these regulatory and legal challenges requires collaboration between regulatory authorities, modern medicine and TM practitioners, researchers, local communities, industry stakeholders, and legal experts. It is important to strike a balance between ensuring consumer safety, quality control, and intellectual property protection while facilitating the integration and commercialization of traditional medicine products. Efforts to harmonize regulations, develop clear guidelines, and promote capacity building can help create a favourable regulatory environment for traditional medicine products and stimulate their economic development. By overcoming these barriers through appropriate policies and strategies G20 economies can harness the economic potential of TM and promote its integration into healthcare systems, leading to sustainable economic development and improved healthcare outcomes.

Policies and Strategies for Promoting Traditional Medicine's Economic Potential

As is clear from the narration of the status of TM in G20 countries, the first and foremost prerequisite is to recognise TMs as medical systems that are complementary and alternative. For this is critical to establish clear and robust regulatory frameworks for TM products and practices. These frameworks should address safety, quality control, product labelling, licensing, and certification requirements. At present, many countries do not have any such regulations. They as well as those who already have certain regulations should ensure that the regulations strike a balance between safety and accessibility, allowing TM products and practitioners to operate within a regulated framework. They should also create mechanisms for monitoring and enforcing compliance with regulations.

Another critical strategic measure for states is to allocate adequate funding and resources for research and innovation in TM. It is necessary to support scientific studies, clinical trials, and evidence-based research to validate the safety, efficacy, and mechanisms of action of TM treatments. Collaboration between research institutions, TM practitioners, and pharmaceutical companies may be necessary to promote innovation and develop new products, and this should be fostered. After all, as India's National IPR Policy (2016) states 'the fertile knowledge resource' of TK should be used to stimulate creation of IP and for that collaboration among the above-mentioned groups is necessary. IP and innovation model is likely to lead to better economic returns.

At the same time, it is also imperative to develop mechanisms to protect TK and traditional medicine practices from unauthorised uses and misappropriation. Towards this it is necessary to establish frameworks for the documentation, preservation, and recognition of TK and to ensure that TM practitioners and indigenous communities receive fair compensation and benefit-sharing for their contributions as in the case of use of biological resources as envisaged under the Convention on Biological Resources.

It is also vital that education and training programmes in TM be developed in a standardised format. In India, ISMs like Ayurveda are taught in subject universities and colleges just like modern medicine. There are regular graduate, post-graduate and research courses with standardized curricula. Similar systems may be established in other countries. It is also necessary to have certification programmes and continuing education opportunities for TM practitioners to enhance skills, knowledge and professionalism among them. It is critical that the system provides for interdisciplinary education that will foster collaboration between TM and modern medicine professionals.

An important policy initiative that the countries will have to do to reap the full economic potential of TM is to facilitate international collaboration and knowledge exchange in the area. They should encourage partnerships, research networks, and academic exchanges among G20 countries and beyond. The countries who already have been using TM should share best practices, research findings, and experiences to enhance the understanding and utilization of TM. This collaboration can also facilitate trade, market access, and the exchange of TM products and services. The countries should encourage cross-border trade and export opportunities for TM products and services.

In a globalized economy, domestic markets need to be developed for TMs just like for other sectors. The authorities should encourage market research, product development, and branding of TM products. This will require initially awareness campaigns to educate the public about the benefits and appropriate use of TM. The governments should support the marketing, branding, and export of TM products while ensuring quality control and adherence to international standards. They should also explore opportunities for traditional medicine-based tourism, wellness retreats, and cultural experiences to attract international visitors and stimulate economic growth. It may also be necessary to provide financial incentives, grants, and loans to support the growth of TM industries in the early stage.

From an economic perspective, availability of international trade data is very important. For regular monitoring, the system of HS codes needs to be extended to TM products. As of now TM products get classified under food preparations like herbal teas or dietary supplements, or drinks with added ingredients or organic compounds, or herbal medicinal preparations for both humans and animals or as animal feed supplements. In the absence of clearly defined classifications, it is difficult to get accurate data on all TM products including MAPs which is necessary to clearly establish their economic importance. An initiative by the G20 in this direction should be highly rewarding. In fact, availability of reliable economic data on manufacturing, service and trade is fundamental to policy-making.

Conclusion

It's important for G20 countries to adapt and implement these policies and strategies based on their unique cultural contexts, healthcare systems, and regulatory environments. By doing so, they can foster the economic development of TM while ensuring patient safety, quality control, and ethical practices. By implementing these policies and strategies, G20 countries can create an enabling environment for TM contributing to their economic development. They can harness the latent potential of TM while ensuring quality, safety, and ethical practices, leading to economic growth, job creation, and improved healthcare outcomes.

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Ayurveda in G20 Countries: Status and Opportunities

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Abstract: This year India has been nominated to be the Presidency of G20 which is a golden opportunity in order to steer the world towards inclusive and sustainable healthcare delivery through traditional medicine. On this background, it becomes inevitable to probe in through the possible status and opportunities for Ayurveda as a part of traditional medicine system in G20 countries. This is an effort to look into the current educational, legal and formal status of Ayurveda in the countries representing G20.

Introduction

G20 countries constitute more than 60 percent of the global population[1] with varying levels of health achievements. Globally, increased pressures on health systems have exacerbated existing resource and capacity constraints. Challenge of accesand inclusion in leaving 'no one behind' that most G20 countries face today includes sustainability of effective UHC within financial constraints, fragmented care models. These challenges can potentially be met with equitable access to safe and quality traditional medicine services and has been acknowledged as such at international platforms like the Astana Declaration in 2018[2]. Under India's Presidency of G20 in 2023, sustained efforts have been made to include traditional medicine as a subject of importance in health related deliberations. Traditional medicine as

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an emphatic discourse in G20 meeting deliberations under the Working Groups, Engagement Groups and other platforms has received tremendous support under India's presidency. This was reflected in the G20 Leaders Declaration in New Delhi in September 2023 that seeks to"*Recognize the potential role of evidence-based Traditional and Complementary Medicine in health, and take note of international efforts in this direction, including WHO's global and collaborating centres, and clinical trial registries*",[3] . This is also a reflection of the changing global perceptions on relevance of traditional medicine for meeting health needs of countries. Earlier, the G20 Health Ministers Declaration under Argentina's Presidency in 2018 stated that, "*Countries may wish to integrate, where appropriate, scientifically proven traditional and complementary medicine, assuring the safety, quality and effectiveness of health services*".[4] The concept of green pharmacy was enunciated during Indonesia's Presidency of G20 in 2022 via the T20 Communique' stated *Green pharmaceuticals and nature-based solutions could serve as potential solutions to current and future health issues. This requires a massive sustainable biodiversity management effort and coordination on the G20 multilateral level to ensure adequate efforts and resources are allocated to achieve the objectives.* [5] Today several G20 countries have a strong tradition and associated policy and regulatory framework for traditional medicine systems while several others have seen a rapid development of regulatory initiatives for integrating traditional medicines in healthcare. G20 consists of countries like India, China, Japan, Korea with strong codified systems, countries like Brazil, South Africa, Mexico and Argentina with strong oral traditions along with countries like USA, Russia, UK, France, Saudi Arabia who are increasingly availing therapies of traditional and complementary medicine systems. The global adoption of Yoga is a testimony to the strengths of traditional health system and could be used as a rallying point for acceptance of G20.

India as of now has Ayush (Ayurveda, Yoga, Unani, Siddha and Homeopathy) systems as a part of traditional medicine wherein following the WHO TM strategy, the objectives for mainstreaming of Ayush have been broadened in the National Health Policy 2017 in India. The National AYUSH Mission is a welcome step focussed on enhancing the AYUSH sector in terms of health services, educational standards, drug quality control and sustainable development of medicinal plants. Central sector schemes offered by Ministry of Ayush provide direct funding of projects related to promotion and development of the AYUSH sector targeting extramural research studies, international cooperation endeavours, public health interventions, and setting up centres of excellence and industry clusters. Thus, Indian Government is encouraging the practice and preach of Ayurveda by supporting all the eminent educational institutions, hospitals and pharmaceutical companies and pitching in to interdisciplinary approaches with various research organizations. Ministry of Ayush, India is playing a pivotal role into propagation of Ayurveda by development of Ayush chairs, facilitating the export and import of Ayurveda medicines abiding by the drug regulations in India and abroad. Overall, USA (34.95 per cent), EU (18.66 per cent) and UAE (5.52 per cent) are the major markets for all three categories of Ayush exports and they contributed to 59.12 per cent of all Ayush exports in 2021 (Pathak and Agarwal, 2023)

Institutionalising Ayurveda in global governance through WHO is already underway. The WHO Traditional Medicine Strategy 2014–2023 was adopted by all Member States at the World Health Assembly in May 2014. Governments and consumers across the globe are considering the aspects of traditional medicine practices and practitioners for improving the outcomes of healthcare delivery worldwide. The key goals of this strategy are to include to support Member States in harnessing the potential contribution of T&CM to health, wellness and people-centred health care, and to promote the safe and effective use of T&CM through the regulation of products, practices and practitioners.(WHO, 2020) Given the prevailing global demand for holistic wellness and increasing regulatory streamlining on herbal/traditional medicine in countries with or without indigenous traditional medicine systems, the status of Ayurveda in G20 countries is assessed in this article.

Ayurveda in Latin American countries

Since last 50 years, many efforts have been put forth in order to introduce Ayurveda in Latin America. This is evident from establishment of Ayurved therapy centres across these countries. Ayurved courses are now being taught at university level after obtaining official recognition in Argentina, Brazil and Mexico. Ayurveda his also adopted as a medical system by the national health systems by Brazil. Besides this, Ayush chairs have been established in Argentina and Mexico. (Berra, 2022) (Berra & Molho, 2010)

Ayurveda in Australia

Australia is dominated by chiropractic profession under the umbrella of Traditional and Complementary medicine (TC&M). The representation of Ayurveda practitioners in Practitioner Research and Collaboration Initiative (PRACI) network was found to be very meagre. The regulations for clinicians of Ayurveda stream are not well defined. National Institute of Complementary Medicine Health Research Institute funded by the Australian Commonwealth Government and New South Wales Government, based at Western Sydney University, one of the largest T& CM research facilities in the area, has incorporated Ayurveda as one of the modalities. None of the universities I Australia offer regular courses in Ayurveda but some government-accredited private colleges offer diploma and certificate level 4 courses.(Matthews, 2004) Recognized Ayurvedic qualifications are offered by the Australasian Institute of Ayurvedic Studies located in Australia and New Zealand focusing on fundamentals, clinical training. Also, diplomas & advanced diplomas comprising clinical training in Ayurveda to become an Ayurvedic practitioner or therapist are available in Australian Institute of Higher and Further Education. Graduates are eligible to attain a membership on completion, in professional association viz. the Australian Natural Therapists Association representing Ayurvedic practitioners in Australia[6] The Health Institute Australasia in Melbourne and Gold Coast runs certain government affiliated diplomas, advanced diploma courses and distant courses in Ayurveda especially for practitioners[7].

In case of regulatory framework for medicines, Ayurveda lies under the category of complementary medicines in Australia and governed by Therapeutic goods administration (TGA) which maintains all the details of licensed companies in a central register. Thus,

due to the heavy metal content and other issues, the acceptance of herbo-mineral formulations is very tough (Bhuyan et al, 2022). Still many companies like Blackmores, Lifespace, Integria healthcare have certain herbal products registered under TGA.

Ayurveda in European Union

In case of EU, Ayurveda is still not acknowledged as an official medical system. In some countries like Germany, doctors have a free choice of therapy, thus, Ayurveda under the ambit of Complementary and Alternative Medicine (CAM) is practised by BAMS graduates after obtaining license as a 'Heilpraktiker' i.e. a practitioner in natural medicine. Ministry of Ayush has collaborated with Germany for some research projects. Certain organizations namely Rosenberg European Academy of Ayurveda offer a Master of Science in Ayurveda program in Germany, Austria and Switzerland. Atreya Ayurveda School in France and Ayurveda point School in Italy also offer courses in Ayurveda. As regards to Drug regulations in Europe, Ayurvedic Medicines fall under Category of Dietary Supplements. To sum up, legalities in terms of education, clinical practice and regulatory framework for drug in Ayurveda are not demarcated till date (Rosenberg, 2022)

Ayurveda in USA

In United States, the first educational standards for Ayurveda were set up by National Ayurvedic Medical Association comprising 500 hours of education. The California College of Ayurveda focuses more on Clinical practitioner training. Apart from full training programs, the organisations also impart correspondence courses, weekend training and Short term seminars. Still, there are no formal regulations available for clinical practice as well as education in USA. California, Idaho, Minnesota, New Mexico and Rhode Island are the five states where in Ayurveda practice has been safe guarded under special laws i.e 'Health freedom acts (Halpen, 2027).

Ayurveda in Russia

Ayurveda started to take roots in Russia after the Chernobyl disaster which resulted in the development of first Ayurvedic Medical Centre in Minsk in 1990. Shortly after this, a special department of Ministry of Healthcare was formed wherein Ayurveda was integrated in the Russian healthcare system due to positive results in paediatric care. Upto 1998, Ayurveda was included in the state register of practices too. Ayurveda Russia–India Association (ARIA) was established in 2005 to introduce certain credit courses in Ayurveda. Institute of oriental medicine under People's Friendship University was established in 2013 which possesses a separate department of Ayurveda. Since then, considerable research along with Indian pharmaceutical companies has flourished. Also, Ayurvedic literature is being published regularly in Russia (Karilyo, 2023) (Ragozin, 2024).

Ayurveda in Saudi Arabia

There is no clear information available on status of Ayurveda in Saudi Arabia pertaining to education and clinical practice after searching online. Some norms are available for Dubai instead.

Ayurveda in South Korea

In case of South Korea, it has its own traditional medicine system named Haanyak with licence to practice since 1950s. Korea has a dual medical system wherein doctors possess both license of

western medicine and traditional medicine. (Ryu et al, 2023). Some of the principles of Ayurveda are similar to traditional Korean Medicine (TKM). Government Republic of Korea has established universities engaged in imparting skills and training in TKM. In Korea, Masan University is the pioneer in introducing syllabus of Ayurveda[8].

Ayurveda in South Africa

In case of South Africa, Ayurveda Courses are offered by The Nelson Mandela School of Medicine in collaboration with Natal University which have Ayurveda faculty at the University. The import of Ayurvedic medicine is allowed to a certain extent here. Ayurveda practice is also recognized and has representation on different Boards of the South African Ayurveda Liaison Committee and African Allied Health Professional Act[9].[14] Ayurveda has gained importance since Kenyan Prime Minister Raila Odinga's daughter Rosemary benefitted with Ayurveda treatment at Sreedhariyam for restoring her vision. India is also planning to set up a Ayurveda Chair in the Durban University [10].

Ayurveda in Canada

In Canada, Ayurveda is still not recognised as a separate medical system but the Canadian Government offers and allows BAMS graduates and post-graduates to practice. Toronto College of Ayurveda is the only institute in North America with Ayurveda physicians. The International Council for Ayurvedic Physicians (ICAP) is registered with Canadian government and boosts the aspirants of Ayurveda to pursue Ayurveda as a profession[11].

The remaining countries like Japan, Indonesia, Turkey and China have their own recognised systems of medicine that are being adopted by their respective governments.

Scope for Ayurveda in G20 Nations

Multilateral cooperation is important for growth of traditional medicines. Some regional cooperation frameworks have been successful, while others have not. For example SAARC remains a poorly integrated group even after 35 years after its genesis whereas sub-regional groupings such as BIMSTEC and other regional groupings like ASEAN are moving ahead with initiatives in cooperation for standardisation and quality control in the sector (Pathak, 2023) . However, the COVID pandemic has shown that the greatest strongholds for traditional medicine include countries like India, China, Sri Lanka form Asia and also countries from African continent like South Africa, Nigeria, Brazil have made a substantial contribution to envisage the potential of traditional medicine globally during the covid pandemic. This will surely pave way for development of inter-operable policy mechanisms in TM in order to facilitate its smoother implementation among the grass root levels. In India, Ministry of Ayush through its various research councils and academic organisations has contributed significantly in addressing the preventive measures during covid, post-covid management of various disorders thereby contributing quality of life.

The success of Global Ayush Investment & Innovation Summit held in April 2022 in Gandhinagar witnessed letter of intents (LoIs) over Rs 9,000 crore in only three days. This event saw participation from more than 30 FMCG companies leading to an expected quantum of jobs for 5.5 lakhs. Summit has been instrumental in making the world aware of impact of Ayurveda and other system of medicines in India in their reliability in healthcare and wellness services across the world[12].

Further, the announcement and foundation stone laid for the WHO Global Centre for Traditional Medicine (GCTM) at Jamnagar, Gujarat, India will help in harnessing the potential of traditional medicine which will naturally aid in global acceptance of Ayurvedic sciences too. Ministry of Ayush is also active through its International Cooperation cell for recognition and promotion of Ayush on international platform. It has already initiated fellowship schemes for foreign nationals, exchange programs wherein Ayush experts are deputed in foreign countries to participate in international meetings, conferences, training programmes, seminars and on special assignment of the Government of India for promotion and propagation of AYUSH Systems including Ayurveda.[13] Further, efforts are also being made for global recognition of Ayurvedic medicinal drugs for their registration with regulatory authorities of foreign countries.

Conclusion

These efforts will surely be fruitful for nurturing the fundamentals of Ayurveda globally leading to its worldwide recognition and legal acceptance in many countries. The G20 platform is a further golden opportunity for India to captivate the attention of all these nations towards understanding and implementation of Ayurveda doctrines in their respective health systems and health policies.

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Research and Development in Traditional Medicine Systems: A Review

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Abstract: The economics of well-being are based on health-based activities. Therefore, it is necessary to reduce the global disease burden by creating a balanced ecosystem which not only influences the climate but also limits disease. There is a need to bring together the different medical systems to address this need. UN agencies and the World Health Assembly have now coined the term 'TCIM' (Traditional/indigenous knowledge, Complementary and Integrative Medicine) emphasizing cultural context, people-centred care and collaborative efforts among different medical systems for one health for all. Traditional Medicine (TM) in India has progressed phenomenally and attempts are to utilize modern scientific developments to further promote it nationally and internationally. This article reviews the status, challenges and initiatives in traditional medicine systems of India.

Introduction

The economics of well-being are based on health-based activities. The spending on global health is 8 trillion USD[1]. The annual estimates of the global disease burden of 30 years starting from 1991, covering 204 countries, territories and subnational units, have recorded 371 diseases and injuries[2]. The annual estimates got interrupted due to the COVID-19 outbreak. The data has shown that there is a rapid epidemiological transition from communicable diseases, maternal and neonatal mortality, and nutritional deficiencies to non-communicable diseases

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(mainly cardiovascular) and injuries in low or middle income countries (LMIC).[3] There is a double burden of both communicable and non-communicable diseases in India. The emerging nutrition transition shows both under-nutrition in children and over-nutrition in adults sometimes within the same household. (Oomen and Suri, 2019) According to national burden estimates published in 2017 using direct mortality and indirect disability data,[4] the diseases prevalent in one part of India were uncommon in another and most of these diseases were avoidable ones. The influence of a balanced ecosystem with preserved biodiversity not only has an effect on the climate but also limits disease. Using a combination of medical systems is now termed by UN agencies and the World Health Assembly as TCIM (Traditional/ indigenous knowledge, Complementary and Integrative Medicine). The proposed WHO definition of TCIM is 'all traditional medicine, complementary medicine and integrative medicine activities, services and resources intended to promote, restore, or maintain health and well-being. The emphasis is on cultural context, people-centred care, collaboration between diverse health practitioners, and a positive vision of health that integrates physical, mental, spiritual and social well-being'. WHO Traditional Medicine Global Summit has included this concept in its Gujarat Declaration, 2023.[5] The endeavour is to undertake preferential care of the patients which may be most suitable to them. MD, PhD programs and research fellowships are planned to promote TCIM.

Health in Ayurveda is not merely a sum of biological processes in humans but also an adaptive response to the environment. Ayurveda and Siddha believe in five elements of nature influencing the body, mind and spirit, namely, air, fire, water, earth and sky (ethereal) – the *panchabhutas*. On the other hand, Hellenistic medicine believed in only four natural elements, namely, air, fire, water and earth. Interestingly BM and Unani Medicine took roots from this Greek medicine. While Unani medicine considers these four natural elements influencing four humors – blood, phlegm, black bile and yellow bile – responsible for maintaining the balance of well-being, BM strayed away much later from these beliefs to become the reductionist system starting with medical enquiries in 1800s, germ theory of Louis Pasteur and genetics by Mendel, epidemiological studies to study the causes and getting further complicated by adopting scientific and technological advances focusing on pathogenesis. So, this development is just more than 200 years old when traditional medical systems concentrating on salutogenesis originated several centuries back as evidenced by various classical texts.

However modern scientific tools are now being used to find answers to systemic biological processes. An example is Ayurgenomics which is an application of genomics to explain the *Prakriti* phenomena and correlating it with the three doshas (*Vata*, *Pitta* and *Kapha*) through the expression of genes and physiological characteristics. Predictive, Preventive, Personalised, and Participatory (P4) medicine is emerging as a new field focusing on a patient as a whole combining ancient and modern medicine through Ayurgenomics to improve mental and physical health. (Wallace, 2020) Today it is important to understand the different approaches of TM across the world to increase respect for this heritage which have immense value in certain scenarios if practiced as TCIM rather than in isolation. In Africa and Americas, the traditional

healers have oral tradition of transmitting their knowledge.[6] As in rural and tribal communities, people have more faith in such traditional healers their inclusion in healthcare programs and research will be culturally appropriate as equitable partners.(Sundararajan *et al*, 2013) Nevertheless, this need to be addressed by health policy makers. According to WHO, 170 countries with TM use different policies, guidelines and regulations.[7] Therefore, creating internationally acceptable standards[8] for TM including, practices, manufacture of products, their registration (to avoid spurious and unsafe preparations), practices and practitioners would serve as a global model for international harmonization which will increase faith in the TM services regarding their safety and effectiveness. (Kumar, 2022) A 'one nation' concept in health cannot be achieved unless this is addressed by WHO for member states using TM.

Status of TM in India

With the formation of the Ministry of Ayush in India, advancements in practice and research using the TM has grown phenomenally. Its support has been well utilized to include TM in the ICD-11 classification, create platforms for enabling easier use of TM in healthcare, standardization of terminologies used in TM, promote innovation and digital health, apply standards to devices and TM preparations in collaboration with the Bureau of Indian Standards and facilitate use of artificial intelligence in TM. R&D however is a component that may require a more concerted effort although India's health and science policies have indicated effective utilisation of traditional knowledge and traditional medicine systems.

The National Health Policy of India, 2017 has indicated a pluralistic health management system envisaging the application of the highest level of health and well-being catering to all ages through preventive and promoting measures undertaken by Ayush at primary, secondary and tertiary levels of healthcare. During COVID-19 pandemic the Ministry of Ayush set up an Interdisciplinary Ayush Research and Development Task Force to initiate research on COVID-19 through Research Councils and National Institutes. There are 140 such studies that were undertaken across the country. The efficacy of *Ayush 64* and *Kabasura Kudineer* was established through multi-centric trials during this period and was recommended by the Ministry for the treatment of COVID-19[9]. In the State of Tamil Nadu, *Kabasura Kudineer* was given to all patients in the BM Hospitals too as a State directive[10]. From an economic point of view the cost-effective judicious use of TM at the preventive stage of the disease itself, for example, treatment of anal fistula by a medicated thread of Ayurveda as compared to surgery (Datta et al, 2025) .

TM in healthcare has a definite role to play along with BM treatment modalities for the patient-centric approach to tackling diseases. The Indian Council of Medical research (ICMR) had followed the multidisciplinary approach in its Composite Drug Research Scheme by collaborating with the erstwhile Central Council for Ayurvedic Research and Council for Scientific and Industrial Research (CSIR) (Chaudhary and Singh, 2011). Later the Golden Triangle Partnership Scheme[11] and CSIR's New Millennium Indian Technology Leadership Initiative (NMITLI)[12] adopted the same methodology of using several institutions of modern medicine, Ayurveda and basic

sciences. The Government has been paying attention to interdisciplinary and multidisciplinary approaches towards attaining this goal. The setting up of the National AYUSH Mission (NAM) is with the aim of providing cost-effective healthcare through TM applications at various levels of health infrastructure. The establishment of an international hub for TM in Gujarat by WHO is a step forward in this direction. Integration of ASU drugs and Yoga with BM are being tried across the country by Ayush Research Councils under the Ministry of Ayush and some private institutes in an attempt to improve healthcare and generate scientific evidence. There have been some notable achievements through such integration in filariasis and in rheumatoid arthritis treatments (National Academy of Medical Sciences, 2023) (Narahari et al, 2011) (Furst et al, 2011) .

While this is encouraging, the challenge faced is the finesse required for carrying out best practices in research. There are various approaches and methods followed in the application of research in BM which is insisted upon but is similar attention being paid to research in TM. In order to address some of these problems and to bring in scientific tools which would help the evidential progress of TM, the Ministry of Ayush has taken the step to have a National Professor and five Chairs, one each for interdisciplinary research, drug development, epidemiology and public health, microbiome and cognitive science to guide research on TM[13].

Changes are going to be brought in the education system, practice and research. Gujarat Ayurved University, Jamnagar, upscaled in 2020 as Institute of Teaching and Research in Ayurveda, is a leading institution among others to use this integrative medicine (IM) approach. In the BM course during the first-year yoga will be taught, with internship in the other systems[14]. Clinical practice and primary healthcare for public health delivery would involve both systems to provide the advantage of a particular system wherever necessary for personalized care. Academic Departments in AIIMS would be started and high priority would be given to research especially training in modern biostatistics and research methodology.[15] Centre of excellence in integrated centres, national integrated protocols, information management systems and sensitization of practitioners of other systems are some of the measures envisaged for implementation shortly.

Challenges in TM research

Various aspects need to be addressed when involving research using TM as the emphasis is being placed on evidence. The following components need to be considered for harmonization:

- Ethical Guidelines
- Regulations
- Design of the research
- Procurement and standardization of test formulations
- Conduct of research
- Publication of the outcomes

Ethical Guidelines

The universal principles of respect for persons, beneficence, non-maleficence and justice and also the EU Global Code for Conduct of Research in Resource-Poor Settings for Collaborative Research (GCC) (the title now changed to Global Code for Conduct of Equitable Research Partnership in 2023) are to be followed while doing research.[16] Since there is growing international demand there is need to have harmonized standards for

GMP (Good Manufacturing Practice) and GAP (Good Agriculture Practice) related to TM (Pathak, 2023).

Scientific rationale: All research has social value. It is important to understand that research based on appropriate scientific enquiry addresses societal needs. Bad science means bad ethics so a scientific review of the research proposal is essential. Any clinical trial that has to be undertaken using modern scientific methodologies should be a collaborative effort between the researchers of TM and BM as equal partners, national or international. The literature survey should be extensive enough to provide a good base for planning the research. Clarifications may be sought whether the product has been ensured of not having adulterants and whether prior information on dose finding, toxicity and herb-drug interaction, if any, has been verified and submitted.

Benefit-Risk assessment: Any proposal should envisage the probability and magnitude of risk/harm that may occur to the participant. Both the researcher and ethics committee should weigh the extent to which it can involve the participant. The ethics committee (EC) would decide on what type of review can the proposal be subjected to depending on the type of risk. Safety reports about adverse events should be sent on a timely basis to the EC, which should address the issue as per the guidelines/regulations of that country.

Informed consent: When double-blind studies are planned, the informed consent document should make it very clear to the participants the likelihood of being enrolled in the placebo/control arm. This is essential to mention because participants should understand that in blind studies there would be different interventions to decide whether to enroll in the study or not as they may prefer TM or BM. The confidentiality clause also should be mentioned clearly. Compensation for participation and injury during the research period should be addressed not only in the submitted proposal but also in the informed consent document. Care should be taken to prevent therapeutic misconception.

Collaborative or interdisciplinary: In every such studies the local practices should be respected. It is advisable for BM researchers to be always associated with another researcher from the TM system when conducting a trial. It would be ideal to have a multidisciplinary expert group to guide the designing of the study and its evaluation.

Access and benefit Sharing: If a community's traditional knowledge has been the base for discoveries with potential commercialization, then they should be beneficiaries too. To prevent bio-piracy, a database should be developed which should be accessible to several Patent Offices across the globe through a non-disclosure agreement. This information should also be made available to R&D institutions and pharma of the country to guide better research and improve quality of manufacture of TM formulations. In biodiversity-rich countries, the untapped tribal knowledge of ethnomedicine can lead to commercialization by patenting of the practice or plant derivatives. According to the Biodiversity Act, prior informed consent of knowledge owners should be obtained to protect their rights. After the development of the product, they should also get access to it and get a share of the benefits that may accrue. This has to be derived prior to initiating research in such cases. In fact, India has set an example by providing for the first time in the world, a 50 per cent share in the commercial gains to a tribal community (*Kani*) in Kerala in

return for its knowledge about a medicinal plant *Trichopus zeylanicus (Aarogyappacha or 'Jeevani')* which has an anti-stress and anti-fatigue action.[17] The benefit sharing would be the ethical responsibility of the researcher/research team to work out appropriate utilization of the returns for the welfare of such communities as done in this case. The San tribe of South Africa had been exploited for a number of years by Western researchers for their traditional knowledge and genetic mapping. They finally succeeded in making the San Code of Research Ethics[18] and released it in 2017. The San tribe leader's statement 'Your house must have a door so that nobody needs to come in through the window. You must come in via the door, that is to say via the San Council'[19] became a slogan to inform researchers that they should discuss a project involving them as equitable partners. Based on this code under the TRUST project, a code for EU researchers was made with four main ethical principles – respect, fairness, care and honesty.[20] Here the 'respect' term meant that the local researchers, community, participants and cultural sensitivities should be respected. If researchers from high-income settings cannot agree on what is acceptable to local stakeholders on their terms, then it cannot be conducted. Again based on the San Code, South Africa has the Indigenous Knowledge System Act, 2019 where the knowledge holders are to be co-owners of that knowledge[21].

Design of the study and role of ethics committees: To anticipate positive results for generalizable knowledge, ample attention need to be paid to the design the study**.** This is important for the EC to ensure whether the research is feasible and protect rights, safety and well-being of the participants. In double-blind study only if there is no other alternative standard of care available should the placebo be chosen in the control arm. If the test intervention is found to be beneficial, ethically it is required to be provided to the participants in the placebo arm. More details about design of the study will be mentioned in later part of this article.

Ethics committee of most of countries may not have the expertise to evaluate TM proposals. It is more feasible in countries with pluralistic medical systems. If the ECs of BM institutions do not have the expertise to review such proposals, an appropriate TM expert should be co-opted or asked to review the proposal to provide comments. ECs reviewing TM should either have members or experts from that particular TM discipline giving their inputs or experts in the related area to give their comments. In India very often this has become a problem, but in Sri Lanka and Nepal being small countries, this is not an issue as TM experts are very much a part of ethics committees. The first independent EC in India to adopt this methodology is the Inter-system Biomedical Ethics Committee (ISBEC), with multi-Indian TM system experts.[22]

Training: Training in research ethics, research methodology, Good Clinical Practice (GCP) and GMP, GAP, GHP (Good Harvesting practices) and Good Collection Practices adapted to the systems are required for best results. In India, it is now mandatory to have prior training in research ethics, GCP, EC management and NDCT Rules.[23] The latter has indirectly mandated the national ethical guidelines.

Regulations

According to the WHO report the number of member states with TM policy and regulations as well as the registration of TM practitioners has increased almost threefold in last ten-year period covered

from 1999 to 2018.[24] Europe is divided in its acceptance of TM. While the regulations of UK and Germany allow the import of TM only as dietary supplements/tonics since 2011, Italy, France and Belgium recognises TM as therapeutics. European Union (EU) has various directives (Traditional Herbal Medicinal Products Directive (THMPD), Food Supplements Directive (FSD) and the Pharmaceutical Legislative Review) which permit use of TM medicines for humans only if they are safe and have quality control standards. Also, they require that they should be used outside EU for 30 years and in EU for 15 years. Another challenge is that in the competing international markets the assessment criteria for testing safety of TM products are the same used for modern pharmaceutical, nutraceutical and cosmeceutical products. In India, there are presently 8065[25] licensed Ayush pharmacies which are GMP compliant and monitored on regular basis[26]. All proposals for clinical research should register in the Clinical Trial Registry.

Procurement and Standardization of Test Formulations

For conducting research using TM formulations it is very important to know about its source or of its ingredients. WHO has brought out guidance in this regard. A literature survey would enable the identification of the plant and easier access to its collection. As synonyms may describe different plants, for example, in India *Brahmi,* is a common local name for both *Bacopa monnieri* and *Centella asiatica*, the TM Section of Uppsala Centre in Sweden is preparing a list of harmonized botanical names of plants from different parts of the world to avoid this confusion. For such work, a good botanist, preferably a taxonomist, should authenticate the information about each plant ingredient and maintain voucher specimens. Standard Operating Procedures (SOP) are required for standardization methodology. The Convention of Biodiversity necessitates the maintenance of a repository of Pharmacopoeial Reference Standards and genetic resources of plants.

All stages of drug development involve CMC (Chemical-Manufacturing-Control), starting from the collection of the plant, identifying it and then developing the product. All these stages require quality control. The Indian classic literature does give details of the standards to be followed for each step. This has validated that the potency of a plant depends on the source, time of collection, season and soil. It is important to identify the plant through pharmacognosy to differentiate it from adulterants. Contamination with pesticides, herbicides, fungus, microbials, toxins and heavy metals should also be checked. Chemical fingerprinting helps to detect batch-to-batch variation. It is preferable to prepare the test formulation in bulk to avoid any such variation in subsequent batch during the conduct of the study and this could be challenging as some of them have very short shelf-life. TM drugs have very complex composition. Therefore, the same rigor that is used for specific chemical quality of synthetic drugs cannot be used for these drugs. The uncharacterized constituents of crude extract may not show the side effects of the active ingredient, e.g., *Sarpagandha (Rauwolfia serpentina.* In India, 'phytopharmaceuticals' term is used for purified and standardized fractions derived from medicinal plant or its parts having minimum four bioactive ingredients.[27] These are now treated as new drugs as per the New Drugs and Clinical Trial Rules 2019[28]. The manufacture of TM/herbal products requires adherence to GMP requirements. Drugs derived

from genetically modified plants through rDNA technologies need to be processed as per existing country specific regulatory procedures for genetically modified organisms (GMO)[29].

As mentioned earlier natural resources get influenced by climate conditions and some are becoming scarce. Therefore, to meet the growing demand alternative synthetic and semi-synthetic analogues of the derivatives of the plant drugs need to be developed. This means there should be greater investment in building capacity in the related scientific fields and cultivation of at least the perennial and annual medicinal plants on a large scale. Wild scavenging can denude the biodiversity-rich forests, so this needs to be checked. The tribal or rural folk should be included in the conservation programs for the trees/herbs. It is necessary to re-plant medicinal plants during the appropriate seasons, prevent exploitation of plant resources, develop propagation techniques like tissue culture and hydroponics, and undertake networking to share resources, humans and infrastructure.

Conduct of Research

Non-clinical Studies: In order to assist the holistic effect system biology approach may be a more useful methodology. The molecular study may provide the mechanism of action studies but it is difficult to determine the ideal models to be used for such studies.

Clinical Studies: Useful data on the safety and efficacy of TM drugs can be obtained through Pharmacoepidemiology and multi-centric observational studies with objective markers. Even repositioning of TM drugs, for new indications, can be followed as it was observed recently during COVID-19 pandemic.

Methodology: Tailoring randomized control trials (RCTs) to explore the efficacy of a TM drug as a holistic trial design based on an individual's constitution and host-disease variability is a challenge. There are several reporting guidelines that indirectly provide guidance for the proper designing of the study, *viz.*, epidemiological observational studies STROBE Guidelines (Strengthening the reporting of observational studies in epidemiology), 2007, and for case reports CARE Guidelines (CAse REports), 2013, and Consolidated Standards for Reporting Trials (CONSORT) for herbal medical interventions(Sikorskii et al, 2009). It is wrong to think that RCTs having a control arm should be double-blind to give unbiased outcomes and its application in TM research is reductionist in nature (Richardson, 2000). SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials), 2013 statement can also be adopted to guide the design of clinical trial protocols. Sometimes it may not be possible to take a double-blind approach, e.g. use of medicated thread (*kshaarasootra*) vs surgical intervention for anal fistula. In RCT using herbals with placebo control, it is necessary to have colour, smell and taste-matched placebo. In partial randomization, the patient preference trial, patient is allowed to choose the preferred treatment (Wasman, 2019).

Single subject (participant) clinical trial or N of 1 is a method used to study on the same patient the outcome of different interventions for a specific complaint. This is to find the best intervention with the least side-effects in the patient (Lillie, 2011). There is a great need to explore sequential trial designs after n=1 study. Nevertheless, limitation of such a study is that it cannot be extrapolated to larger numbers of patients. Sometimes careful

and well-monitored observational studies (Patwardha and Mashelkar, 2009) may provide more valuable information on the dosages suiting the patient's constitution, side effects/ rare adverse events and the drug-herb interaction. Studies of ICMR on traditional remedies and NMITILI projects of CSIR (Council for Scientific and Industrial Research) had adopted reverse pharmacology approach which has three stages, namely, experiential, exploratory and experimental (Nandini et al, 2006). Other countries also accepted this methodology. Based on types of outcome expected, Single case design, black box design, stepped wedge design, ethnographic study, quality of life (QoL) studies and qualitative studies are based on the type of outcome that is expected. It is desirable to conduct Pilot studies first when experimenting with a new treatment. Now newer methodologies have emerged – Adaptive trials, Umbrella and Basket trials etc. The latter two are applied when using biomarker/ genetic basis for response. In the wake of COVID-19 pandemic, platform trials like RECOVERY trial of UK became more popular to find more pragmatic solutions in a shorter period. Whenever possible, the principles and the concomitant non-drug modalities of treatment like yoga and lifestyle correction as advocated by the TM systems should be retained.

Body complexities can sometimes confuse the outcome results of research when TM therapy is seen to give a definite positive effect in practice which the statistical analysis may fail to prove. As Tröhler points out (Howard, 2001) the methods used have to facilitate the interpretation of the sum results of 'arithmetic observationalists and experimentalists'. Adaptive designs may be a better option to undertake as they allow for methodological and statistical modifications during the period of trial. Analytic methodology will also have to consider the response of body, mind and genetic make-up. In placebo-controlled RCTs, analysis of outcome should factor the placebo effect.

A multidisciplinary approach involving good collaboration between TM and BM practitioners as a team works well for the scientific validation of the efficacy of TM. If the public, healthcare providers and policymakers are to make informed decisions on using TM drugs, then it is essential to provide sufficient information on their safety and efficacy.

The clinical trials should be conducted following GCP norms and appropriate policy/ethical guidelines as brought out by the national Governments from time to time but this calls for a sustained financial support from government and industry of the research community.

Integrative Initiatives: Interdisciplinary and integrative approaches can bring out better results for implementing effective healthcare. In India, Regional Research Laboratories, Jammu and Seth G.S.Medical College and KEM Hospital had used integrative approach to study TM. As mentioned above the Composite Drug Research Scheme, Golden Triangle Partnership Scheme and NMITLI are further examples of this approach with various scientists, BM and TM experts coming together to find the evidence about efficacy of combining strengths for finding effective treatment modalities. Much later, Andrew Weil from the University of Arizona, US initiated Integrative Medicine (IM) in USA. (Melchart, 2018)

In fact, IM is a close collaboration between system partners for patient-centric treatment in order to reduce

morbidity and mortality. Recognizing the importance of this new strategy NCCAM (National Centre for Complementary and Alternative Medicine), an NIH (National Institutes of Health) institute in USA, changed its name to NCCIH (National Centre for Complementary and Integrative Health). Several academic centres in US, EU countries, Africa, Latin America and Asian countries have launched IM initiative (Kumar and Dua, 2022). There is no single model for integration of the multi systems for more healthcare. Working in silos as separate medical system streams causes high healthcare cost which integrative medicine can bring both from the view of cost and compliance.

Strategies: To understand the importance of different medical systems working together, the strategies that can be applied can be at education, practice, research and funding levels. Mostly countries in the Eastern region teach a course that combines TM and BM, humanities, local philosophy and culture, most prominent among them being China and S. Korea. India too is going to change the medical teaching by incorporating topics from TM in BM institutions.

Publication of the Outcomes

It is necessary to publish the results of a research project for planning strategy for IM. Negative results should also be published despite reservations. It will also inform the research community about not repeating the mistake and thus curb research waste. During COVID pandemic this was very important. Case reports and case series also can give ample information about designing studies to validate the outcome. Systematic reviews are also a useful methodology for modifying practice guidelines. Modern scientific tools can be used to find out solutions and digitally capture the details enabling analysis and dissemination of results. The challenges for good publications are how to tackle big data since there is a lack of common standards and centralised data, a lack of human resources conversant with IT processes to analyse hardware and software issues and a lack of training in all these areas.

Conclusion

In a global scenario, equitable distribution of healthcare would reduce the economic and health divide. In 170 countries with TM there are different approaches to policy, guidelines and regulations. Different medical systems need to be integrated and there should be continuity of care for universal healthcare. In some countries, the local community has more trust in the tribal practitioners of medicine. The local practices, practitioners and researchers should be respected and their cooperation sought for implementing healthcare programs. In India, TM has incorporated many modern developments for promoting it. The practice of TCIM as integrative medicine is going to be the future of healthcare globally. The use of modern technologies like the use of artificial intelligence, new analytical methods in phytopharmacy and public health measures hold more promise in future. However, for research, many gaps need to be addressed especially research methodology, ethical guidance and regulations. The manufacture of good quality and standardised formulations, both in practice and research, is a major challenge as also choosing the appropriate method for clinical trials. International efforts are on in taking TM more seriously with WHO taking the lead in a big way. The Health Ministers of G20 have also given encouraging assurance

to promote an integrative approach towards 'one health, one nation and one world'. The recently held G20 Summit in September 2023 and the New Delhi Leaders' Declaration[30] stating r*ecognize the potential role of evidence-based Traditional and Complementary Medicine in health, and take note of international efforts in this direction, including WHO's global and collaborating centres, and clinical trial registries* further reaffirms the need for stronger R&D in TM for effective globalisation of these systems in health practices.

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The Anthropological Study of Traditional Medicine in South Africa: Unveiling Complexities, Nurturing Traditions

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Abstract: This comprehensive anthropological study delves into the intricate tapestry of traditional medicine in South Africa, spotlighting its significance, indigenous knowledge protection, and emerging challenges. The study's exploration encompasses the socio-cultural, economic, and health dimensions of traditional healing practices, highlighting the vital role of herbal remedies and spiritual healing within the nation's diverse communities. Through an anthropological lens, this article elucidates the promotion and protection of traditional knowledge and indigenous knowledge systems, focusing on traditional medicine within the South African context. The article highlights the dual health care system, the role of traditional health practitioners, regulatory developments, challenges, and the imperative for collaboration between traditional and modern healthcare systems. With insights drawn from historical narratives, cultural practices, and legislative developments, this article sheds light on the symbiotic relationship between tradition and modernity in the realm of health care.

The paper's culmination underscores the importance of nurturing traditional medicine's role within the framework of sustainable development. Acknowledging traditional healers' vital role as holistic caregivers, economic contributors, and preservers of cultural heritage, this study advocates for comprehensive efforts to protect, promote, and integrate traditional medicine into the nation's evolving healthcare landscape.

Introduction

In the diverse cultural landscape of South Africa, traditional medicine stands as a cornerstone of health and well-being. Rooted in centuries of indigenous wisdom and practices, traditional medicine has evolved into a thriving industry, shaping the health landscape

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and offering a unique glimpse into the interplay between tradition and modernity. This anthropological study embarks on a journey to unravel the intricate tapestry of traditional medicine in South Africa, exploring its economic significance, the role of traditional health practitioners, regulatory developments, challenges, and collaborative efforts aimed at harmonizing traditional and modern healthcare systems. Through a comprehensive anthropological lens, we delve into the promotion and protection of traditional knowledge and indigenous knowledge systems, shedding light on the evolving discourse surrounding South African traditional medicine.

Socio-Cultural Significance

Traditional medicine (TM) in South Africa is intricately woven into the cultural fabric, with its roots extending into an ancient tapestry of practices, rituals, and communal beliefs. Throughout history, communities have sought solace and healing from traditional healers, diviners, and herbalists to tend to a range of afflictions—both physical and metaphysical. This reliance on traditional healing practices is deeply enmeshed in the foundational African philosophy known as Ubuntu, a concept emphasizing interconnectedness and shared well-being. Good health relates to ancestors and community relations, embodying Ubuntu (Mbiti 1990 cited by White, P., 2015).

In the context of healing, Ubuntu prompts a shift in perspective—from viewing health solely through the lens of individual ailments to considering the broader implications for the community. When an individual falls ill, the community recognizes that it isn't solely the individual's well-being at stake, but rather a collective concern. This understanding is reflected in the practices of traditional healers, who address not only physical symptoms but also delve into the spiritual and psychological aspects of their patients' lives. The traditional healer's role goes beyond healthcare to advising in various life aspects (White, 2015). These healers, diviners, and herbalists act as conduits of communal well-being, working to restore balance not just within individuals, but within the fabric of the entire community. As Mbiti (1990) aptly phrases it, "I am because we are, and since we are, therefore I am." This interconnectedness resonates through collective consciousness, fostering shared responsibility for each other's health and welfare.

As Ubuntu permeates the landscape of TM, it prompts individuals to recognize their shared responsibilities. When someone receives healing, it's not only a personal transformation but also a reaffirmation of the intricate bonds that tie the community together. This philosophy instils empathy, compassion, and collective care—a reminder that one's well-being is intimately linked to that of others. Thus, the practice of traditional medicine doesn't exist in isolation; it thrives within a communal context, guided by the timeless wisdom of Ubuntu.

The cultural significance of TM is deeply ingrained in South African communities. Practices may vary by region, depending on tribal customs and traditions. The process of harvesting medicinal plants is guided by spiritual values and customary laws, emphasizing sustainability and respect for nature. Traditional healers establish a profound relationship with plants and animals, viewing themselves as integral parts of the ecosystem.

The phrase 'traditional medicine' has become a catchword among the

peoples in all countries in Africa. This is partly because the use of herbal remedies has gained popularity worldwide and the exploitation of these remedies has become a multimillion industry. The term 'African traditional medicine' (ATM) is not synonymous with 'alternative and complementary medicine'. African traditional medicine is the African indigenous system of health care and, therefore, cannot be an alternative. (Kofi-Tsekpo (2004) cited by White, P., 2015)

South African traditional medicine thrives within a healthcare landscape intricately woven with holistic healing. Unlike the compartmentalized approach seen in modern medical practices, traditional medicine embraces a comprehensive view of health that encompasses physical, spiritual, and social dimensions. This holistic perspective is deeply rooted in the cultural fabric, drawing strength from tradition, spirituality, and community bonds. The interconnection between health and holistic well-being resonates across generations and communities, vital for harmonizing traditional and modern healthcare systems (Sobiecki, 2014; White, 2015).

Central to the holistic healing approach is the profound connection to ancestral spirits. At the heart of South African traditional medicine are the custodians of indigenous knowledge—traditional health practitioners (THPs). These healers, embodying ancestral wisdom, bridge the realms of the physical and spiritual, offering care beyond bodily ailments. As Sobiecki (2014) states, diviner healers use observation and experience, diagnosing with the aid of communication with ancestors and the throwing of bones.

Southern Africa has two main types of traditional health practitioners: herbalists and diviners. Diviners, considered spiritual specialists, use divination to communicate with ancestral spirits to diagnose patients' misfortunes or medical conditions. Both types use plant medicines for spiritual healing (Sobiecki, 2014). Diviner healers diagnose aided by ancestral communication and use plant medicines.

The herbalist healer dispenses 'muthi' (medicine) made from natural substances such as herbs, bark, roots, leaves, blood or parts of animals, or seawater. Ill health may result from ancestral spirits, sorcerers, or witches. Traditional medicines counteract these forces and strengthen resistance. The traditional healer aims to rectify imbalances on physical, spiritual, or social levels, practicing holistic medicine by addressing the whole person and relationships (Sobiecki, 2014). This healer plays a vital role where people accept that nature, humans, and spirits are within the world, using medicines to influence these forces on physical, psychological, and spiritual/transpersonal levels (Sobiecki, 2014). According to (White, P., 2015), traditional healers advise clients on physical, psychological, spiritual, moral, and legal matters, understanding ancestral spirits and witches. Chinsamy (2023) notes a preference for traditional practices despite modern healthcare availability.

These interactions offer insights into physical and spiritual health, highlighting the link between the individual and ancestral lineage. Ancestors mediate between the living and spiritual realm, underscoring the holistic nature of healing—transcending the physical into spiritual well-being. Health amongst Africans includes the well-being of ancestors for their protection of the living (Iroegbu 2005). Herbal healers use plants alongside spiritual input to understand

and cure illness. Good health involves good relations with ancestors and the community.

THPs contribute beyond healthcare, preserving culture, offering spiritual guidance, and uniting communities. They transmit traditions and bridge spiritual and material worlds, exemplifying the interplay between health and culture (White, 2015). The holistic paradigm raises questions for modern healthcare. How can modern medicine include spiritual and communal dimensions? How can ancestral wisdom resonate in clinical settings? Harmonizing systems for comprehensive and culturally sensitive care is crucial.

The holistic approach in traditional medicine bridges systems, complementing modern practices. Acknowledging spiritual and social health enables modern healthcare to address well-being within cultural contexts. Collaboration between traditional practitioners and modern professionals is vital, each offering unique perspectives. Synthesizing approaches fosters an environment where health balances body, mind, spirit, and community.

South Africa's healthcare, steeped in holistic traditions, understands health as multi-dimensional. Ancestral spirits and communal bonds interweave well-being, demanding harmonization of traditional and modern systems for comprehensive care. Cultural heritage guides tradition and modernity toward holistic health and well-being for all South Africans.

South African traditional healing involves ritual practices that vary by region. Psychological, social, and spiritual aspects constitute holistic treatment compared to Western biomedicine. Urban areas see traditional medicine growth despite Western medicines (Jäger, 2005). Diviners diagnose using communication with spiritual forces like ancestors and deities. Divination is integral to African treatment (Omonzejele 2008, Olupona 2004 cited by White, P., 2015, Truter, 2007)

According to the Bushbuckridge community in Mpumalanga, South Africa, harvesting medicinal plants is guided by the spiritual values of the people and regulated by customary laws promoting sustainability. Traditional healers communicate with ancestors during plant harvesting to ensure the medicines' efficacy. Rules linked to seasonal collection exist, transgressions having consequences like jeopardizing rains. Harvesting for immediate use prevents over-collection. The healers' bio-spirituality stems from an intimate and sacred relationship with nature, treating it with love and respect. Their knowledge, dreams, and intuitions crucial for healing are based on seeing themselves integrally connected to nature (Elmien Du Plessis: 2011).

Traditional Medicine Trade and Economic Significance

The vast green landscapes of South Africa offer a rich tapestry of botanical diversity, providing a bountiful source of healing and nourishment. This ecological bounty, coupled with a growing demand for medicinal plant species, has nurtured the traditional medicine trade into a thriving industry. This symbiotic relationship between nature and culture has nurtured the growth of the traditional medicine trade, transforming it into a robust and thriving industry.

As Bareetseng (2022) aptly notes, "The medicinal plant trade is a key rural industry and business incubator." The dynamic interplay between ancient wisdom and contemporary needs have paved the way for the traditional medicine trade to establish itself as a cornerstone of

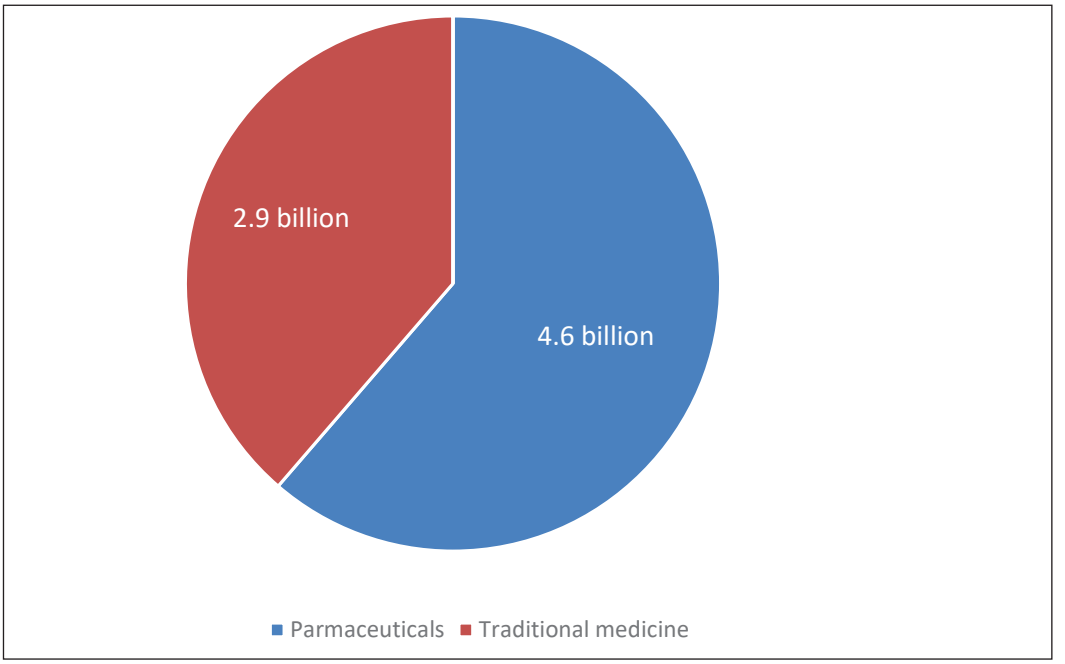
rural economies. The very landscapes that have cradled generations of traditional healers are now nurturing an industry that bridges tradition and commerce.

The traditional medicines trade in South Africa is a large and growing industry. Like many African countries, South Africa is rich in plant species and the demand for medicinal plant species locally and internationally, is rising. The medicinal plant trade is a key rural industry and business incubator. (Bareetseng, 2022). There are some 27 million consumers of traditional medicine and the trade of these medicines contributes to an estimated R2.9 billion to the national economy. The industry is estimated to create more than 450 000 informal jobs, mostly rural women, and there are about 300 000 traditional healers providing a service to about 80per cent of the population mainly from rural areas (Mander, 2007) Most of these people consult a traditional health practitioner for plant based traditional medicine to meet their primary health care needs and even cultural or spiritual purposes. These consumers are from a diverse range of age categories, education levels, religions and occupations. It was estimated that there is 500 traditional healers for every 100,000 people as opposed to 77 medical doctors for the same population. (Msomi, 2023)

The predominant source of medicine for traditional healers is indigenous plants, with at least 771 plant species recorded in the trade in South Africa including the ten most popular traditional medicinal plants outlined in Annexure A. An estimated 20 000 tonnes of indigenous plants are harvested from grasslands, forests, woodlands and thickets in eastern South Africa every year, with only a few tens of tonnes (maximum 50 tonnes per annum) being cultivated. (Mander, 2007)

The opportunities generated by the trade in traditional medicinal plants

Figure 1: Market value of medicinal products in South Africa: 2021



Source: Global data & Future works

and products in South Africa include consumption, retail, processing, wholesale, transport, harvesting, and plant source. Most of this value does not enter into the formal trade and therefore is an addition to the Gross Domestic Product (GDP) and is equal to 5.6per cent of the National Health budget (Mander, 2007, Msomi, 2021)

Studies have shown that the consumption of traditional medicine is not only confined to the poor, rural and uneducated uses but rather the consumption is spread across many sectors of the Black African population in most parts of Africa including South Africa where it is an entrenched cultural practice. The average South African consumer of traditional medicines uses 750g of medicinal plants a year. It is estimated that in South Africa some 128 million courses of traditional medicine treatments are prescribed per year, resulting in the consumption of approximately 20 000 tonnes of plant material, most of which is indigenous. (Mander, 2007).

The traditional medicine trade extends beyond healing, significantly impacting rural economies and livelihoods. The demand for indigenous plants fuels a bustling industry, creating jobs for rural women, healers, traders, and harvesters. The informal nature of the trade raises questions of sustainability and formalization, while underscoring its economic importance (Bareetseng, 2022; Mander, 2007).

At the core of the traditional medicine trade lies the demand for indigenous plants—a demand that sustains an intricate web of economic activities. The trade, beyond its economic dimensions, becomes a conduit for the preservation of cultural heritage. Indigenous plant species not only hold healing properties but also embody cultural narratives and ancestral knowledge. The trade, therefore, becomes a vessel through which these stories and traditions are carried forward, intertwined with economic prosperity.

The traditional medicine trade's economic importance is unquestionable, yet the informality of the trade raises concerns about sustainability and formalization. The trade's foundation rests on informal networks, from street markets to home-based businesses. As Mander (2007) reflects, the trade operates as a parallel economy, influencing the national economy beyond formal channels. This duality presents a challenge, but also an opportunity—a call for policies that harness the economic potential of the trade while ensuring its sustainability.

The traditional medicine trade of South Africa is not confined to the pages of history; it is an active force that shapes contemporary economies and communities. It exemplifies the intricate dance between tradition and commerce, heritage and progress. As indigenous plants are traded, their economic significance resonates far beyond financial transactions, weaving livelihoods, empowerment, and cultural preservation into its intricate fabric. The trade's evolution is a testament to the resilience of ancient wisdom in the face of modern dynamics, a reminder that even in the realm of commerce, the echoes of tradition continue to resonate.

Traditional Knowledge Protection and Biodiversity

The interdependence of traditional knowledge and biodiversity is particularly pronounced in the context of healing through indigenous plants, prompting discussions on the imperative need for their preservation. The utilization of these plants by indigenous communities not only underscores their deep-rooted connection

to the natural world but also highlights the critical role of traditional knowledge in maintaining biodiversity. As such, the discourse extends beyond the realms of health and healing, encompassing broader ecological and cultural dimensions (Alves,2007).

However, the informal trade of these plants introduces a concerning aspect—over-harvesting and sustainability. The demand for these natural resources can lead to their depletion if not managed effectively. This concern calls for a delicate balance between utilizing these plants for healing purposes and ensuring their survival for generations to come. The fragility of certain species further underscores the urgency of addressing this issue.

In addressing the challenges posed by the informal trade of medicinal plants, collaborative efforts emerge as a vital strategy. These efforts entail partnerships between various stakeholders: traditional healers, local communities, and researchers. Each group brings a unique perspective to the table, forming a collective synergy that can lead to sustainable solutions. Traditional healers, as holders of ancient wisdom, provide insights into the proper and ethical use of these plants. Local communities, deeply intertwined with their natural surroundings, offer context-specific knowledge that is invaluable for sustainable harvesting and management practices. Researchers contribute scientific understanding, helping bridge the gap between traditional wisdom and modern conservation practices (Mazzocchi, 2006).

This collaborative approach can serve as a cornerstone for safeguarding both traditional knowledge and biodiversity. By working together, these stakeholders can collectively develop strategies that balance the medicinal needs of communities with the ecological needs of the environment. Moreover, this cooperation helps create a sense of ownership and responsibility among all involved, nurturing a shared commitment to preserving the delicate equilibrium between cultural practices and the ecosystem.

Scholars have highlighted the significance of such collaborative endeavours. Bareetseng (2022) underscores the urgency of integrating traditional knowledge into conservation efforts, stressing the need for partnerships between indigenous knowledge holders and formal conservation bodies. Similarly, Mander (2007) emphasizes the potential of collaboration between traditional healers, local communities, and researchers in achieving sustainable use of medicinal plants and protecting biodiversity.

The utilization of indigenous plants for healing serves as a poignant reminder of the intertwined relationship between traditional knowledge and biodiversity. While the informal trade of these plants raises concerns about sustainability, collaborative initiatives that bring together traditional healers, local communities, and researchers can pave the way for effective preservation strategies. These efforts honour the wisdom of the past while securing a greener, healthier future for both cultural heritage and the natural world.

Regulatory Landscape and Collaborative Efforts

South Africa operates a dual healthcare system, with around 26.6 million individuals utilizing both traditional and Western healthcare approaches. Traditional medicine in South Africa holds significant importance, not viewed as an inferior alternative but as a necessary treatment for health issues not adequately

addressed by Western medicine. However, this industry suffers from informality and fragmentation, lacking unity. Calls have arisen for formalization to enhance the economy and entrepreneurial aspects of African traditional medicine, leading to engagements with financial institutions (Msomi, 2021). Presently, traditional medicines are sold without proper registration and regulation, hindering their coverage by medical aid schemes and prescription by healthcare practitioners (le Roux-Kemp, 2010).

Historically, policies and laws regarding traditional healing have evolved. Colonial influences led to the condemnation of African medical practices as "heathen," "primitive," and "uncivilized," resulting in outlawing (Pretorius 2004, cited by Summerton J. 2006). These biased perspectives persist in academic literature, labelling traditional medicine as unscientific or irrational (Sobiecki, 2014). However, South Africa has made strides in integrating traditional and complementary medicine within its legislative framework since 1994 (Kaya, 2023). Herbal medicines are easily accessible through various channels, including traditional healers, contributing to enhanced primary healthcare accessibility (Cocks and Møller, 2002).

Acknowledging the reliance on traditional medicines, the South African government, a member of WHO, supports policy formulation for traditional medicine (Department of Health, 2015). The Traditional Health Practitioners Act of 2004 marked a significant milestone, legally recognizing traditional health practitioners and emphasizing their rights, aligning with the Constitution's principles (RSA 2005, RSA 1996). The Act established the Traditional Health Practitioners Council of South Africa (THPCSA) in 2006, fostering cooperation among diverse practitioners. The THPCSA oversees registration, training, and practice control, elevating traditional medicine's credibility (Manesis S, 2023).

A new directorate, the Directorate: Traditional medicine, (DTM) was established to manage the work related to TM within the National Department of Health. The vision of the DTM was to advance the contribution of TM to the health and well-being of the population with the mission to facilitate the institutionalisation of TM in the National Healthcare System (NHS) through validation and production of safe and effective TMs and the promotion of TM practice based on a sound legislative and policy framework. The DTM served to coordinate all activities relating to ATM in liaison with units of TM at provincial level and other government departments and statutory research councils such as the CSIR, the MRC and the Agricultural Research Council. (Department of Health,2008)

South Africa regulates herbal medicines under the Medicines and Related Substances Act, 1965, enforced by the South African Health Product Regulatory Authority (Bareetseng, 2022). Collaboration opportunities between traditional and Western health practitioners exist, with traditional health practitioner organizations playing a pivotal role. However, challenges arise due to the heterogeneity and lack of organization among traditional practitioners (Summerton, 2006).

Efforts to commercialize African Traditional Medicine (ATM) have led to the creation of the Traditional Health Practitioners Business Council (THPBC), aiming to boost the economy through strategic partnerships (Msomi, 2021). The main aim is to commercialize African

Traditional Medicine (ATM) through value action in order to grow the South African economy. In order to achieve this strategic partnership with the government and research institutions need to be formed in recruiting Traditional Health Practitioners (THPs) with entrepreneurial aspirations through their ATMs and other products. (Msomi, 2021). An agreement has been reached to formalize a relationship between the University Of KwaZulu-Natal and the THPBC which will facilitate collaboration between the parties in the area of training, research and development around African indigenous knowledge systems and medicine opportunities and development. The main purpose of this agreement is to support entrepreneurship in the field of traditional medicine; identify new traditional medicine related training and research opportunities and niches for entrepreneurs; identify areas in which there is need for high level human resources at all levels (certificate, undergraduate and postgraduate); facilitate the establishment of critical infrastructure for traditional medicine activities; and to promote agricultural methods aimed at preservation and conservation of indigenous medicinal plants. (Msomi, 2021, Kaya 2023)

Tertiary institutions contribute by researching traditional medicine's efficacy and properties. While chemical studies are common, research on the cultural aspects of South African medicinal plants remains scarce, partly due to biases against traditional medicine (Sobiecki, 2014). Public sector investment is needed to support the sustainability of the traditional medicines trade (Mander, 2007). Informal trade in traditional medicines is significant, often lacking stability and hygiene.

In acknowledging the important role of traditional medicine in the informal economy local government structures have shown great interest in improving the conditions for informal medicinal plant traders. This trade also contributes immensely in sustaining the livelihoods of people in both rural and urban areas. It also assists in easing the pressure in an already overstretched formal health system. An example of how local municipalities assist traders of medicinal plants is that of the eThekwini municipality in Kwa-Zulu Natal. Efforts by local governments, such as eThekwini Municipality in Durban seek to improve conditions for traders and support local economies. The Warwick herb market functions within the context of the Inner eThekwini Renewal and Urban Management Program (ITRUMP). ITRUMP is part of eThekwini Municipality's initiatives towards sustainability, urban development, and management of the informal economy. (Xaba et al., 2022).

Challenges and Bridging the Gap

Despite the inherent potency of traditional medicine, challenges persist, mirroring the complexities of coalescing tradition and modernity. The informal nature of the traditional medicine trade, while contributing significantly to livelihoods, presents regulatory gaps and quality control concerns. As le Roux-Kemp (2010) asserts, "Without the appropriate registration and regulation, these medicines are currently sold without any control."

Furthermore, the schism between traditional and modern healthcare systems necessitates the bridging of knowledge gaps and fostering greater understanding. This endeavour requires embracing cultural diversity, respecting traditional healing practices, and dispelling misconceptions. The coexistence of traditional and modern

healthcare systems not only enriches health options but also underscores the importance of collaborative coevolution.

Mistrust between THPs, conventional medical practitioners and scientists remains a barrier to mainstreaming, product development and testing ATMs. Furthermore, the lack of specific training in ATMs in many academic and health institutions may reduce the potential for the inclusion of ATMs in scientific and research agendas (Mutombo et al.,2023)

Despite the abundant natural resources and the anecdotal value of traditional medicine, ATMs remains under-represented and underused in conventional health settings in Africa, as demonstrated during the pandemic. (Wang, 2019)

The harmonious coexistence of tradition and modernity within South African traditional medicine amplifies the nation's cultural identity while nurturing economic empowerment. As the traditional medicine trade flourishes, it uplifts communities and fosters economic resilience, particularly among women in rural areas. The symbiotic relationship between traditional health practitioners, researchers, and policymakers forms the bedrock of this coexistence, where indigenous knowledge is preserved and enriched through collaborative efforts.

Conclusion

In the intricate tapestry of South African traditional medicine, threads of tradition, culture, health, and economy are interwoven. This anthropological exploration highlights traditional medicine's significance as a holistic healing practice, an economic driver, and a cultural heritage repository. South Africa's integration of traditional medicine into modern healthcare systems showcases its commitment to inclusivity and cultural preservation. By comprehending its intricacies, promoting collaborative research, and formulating inclusive policies, the nation can safeguard indigenous knowledge, empower communities, and harmonize traditional and modern healing practices. Through these partnerships, regulatory frameworks, and knowledge exchanges, South African traditional medicine thrives as a vital element in the nation's story, linking the past and enriching the lives of its diverse populace.

While institutional research and collaboration have yielded substantial progress and benefits, an urgent need exists to establish guidelines and regulations for cooperation and integration into the mainstream healthcare and clinical settings. There is a need for the development of new protocols, modification of existing ones, or the endorsement of appropriate existing protocols to ensure integration is done in a way that maximises the potential benefits of ATMs while minimising the risks of inappropriate promotion and misuse. Educating conventional healthcare providers about African traditional medicine and the roles of traditional health practitioners will be pivotal in cultivating understanding and mutual confidence between these approaches, ultimately enhancing healthcare services.

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Role of Standardization and Quality Control in Manufacturing of Herbal Medicines

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Abstract: This Herbal medicine has been an integral part of traditional healthcare systems worldwide for centuries, offering a plethora of therapeutic options. As the global interest in herbal medicine continues to rise, ensuring the safety, efficacy, and quality of herbal products has become paramount. There is a need to delve into the challenges associated with standardization and quality control, regulatory aspects, and emerging technologies to meet these demands. This article explores the relevance of standardization and quality control in the context of herbal medicine, shedding light on the importance of these processes for both consumers and the scientific community.

Introduction

Herbal medicine has been used as oldest forms of healthcare across different cultures and civilizations for millennia. Herbal medicine has been rooted in traditional knowledge systems involving the use of plants and plant extracts to treat a wide range of ailments (Ahmad *et al.*, 2014). Globally, it is estimated that a significant proportion of the world's population still relies on herbal medicine as their primary form of healthcare, particularly in regions where access to modern medicine is limited (Karunamoorthi *et al.*, 2012). Furthermore, the World Health Organization (WHO) recognizes the integral role of herbal remedies in primary healthcare systems of many countries. Beyond its direct therapeutic application, herbal medicine also serves as a foundational resource for the pharmaceutical industry, with numerous modern drugs being derived from plant compounds. As

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globalization fosters increased exchange of knowledge and practices, the significance of herbal medicine continues to grow, warranting rigorous scientific research and integration into contemporary health paradigms.

Herbal medicine and allopathic pharmaceuticals present distinct modalities of treatment, particularly when evaluated in terms of their active compounds. Herbal medicines predominantly consist of complex mixtures of phytochemicals, wherein the therapeutic effect may be attributed to the synergy between multiple compounds rather than a singular entity (Yarnell, 2015). This multifaceted composition can lead to holistic therapeutic actions but also introduces challenges in standardization and consistent dosing. In contrast, allopathic pharmaceuticals generally contain a single, well-defined active ingredient whose concentration is precisely controlled (Yuan *et al.*, 2016.). This allows for consistent dosing, efficacy, and predictable pharmacokinetics. Furthermore, while the pure active compounds in pharmaceuticals undergo rigorous testing for safety, efficacy, and metabolic interactions, herbal preparations, with their myriad compounds, present challenges in fully elucidating their pharmacological profiles and potential interactions. This distinction emphasizes on the importance of bridging traditional knowledge with modern scientific methodologies to ensure both safety and efficacy in therapeutic applications.

Historical Perspective of Herbal Medicine Uses and Associated Challenges

Herbal medicine, often referenced as 'traditional' or 'alternative' medicine, is entrenched in the history of global

Table 1: Comparison of key ingredients in Allopathic and Herbal medicines

India	• **Ayurveda:** Balancing Vata, Kapha, Pitta • **Sidha:** Popular in Southern part of India
China	• **Traditional Chinese Medicine** • Balancing Yin & Yang • Maintaining circulation of Energy (Qi)
Greece	• **Unani:** Based on teachings of Hippocrates and Galen
Japan	• **Kampo:** Influenced by TCM but adapted to Japanese customs
Indonesia	• **Jamu:** Natural materials, such as roots, bark, flowers, seeds, and fruits to prepare traditional remedies

Source: Author's compilation based on various sources.

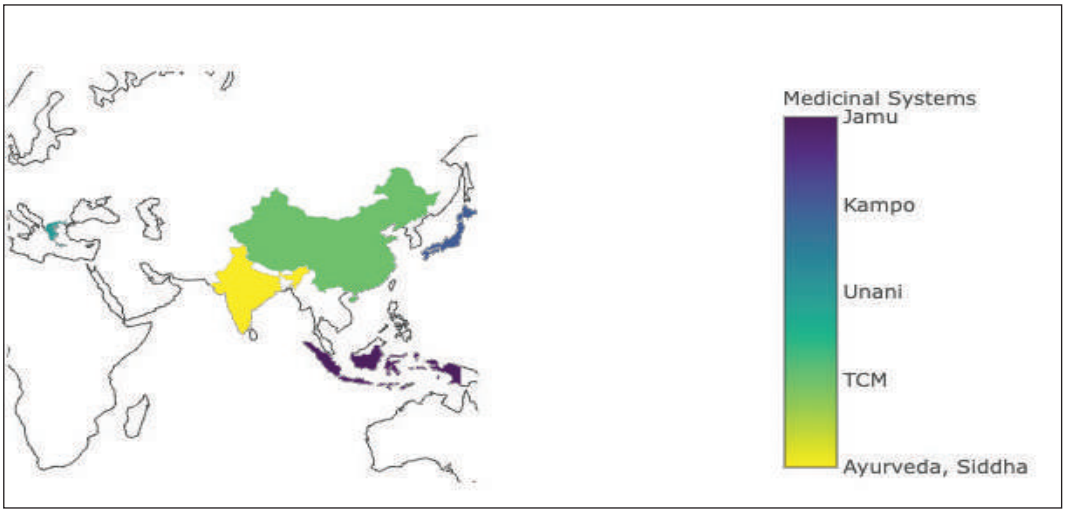
civilizations (Urquiza-Haas & Cloatre, 2022). Before the emergence of contemporary pharmaceuticals, medicinal plants served as primary therapeutic source. The book *The Devine Farmer's Classic of Herbalism* was compiled in China about 2000 years ago is the oldest known herbal text in the world and the Atharva Veda of India documented vast herbal collections, elucidating plant properties, applications, and recommended dosages (Narayanaswamy, 1981; Wachtel-Galor & Benzie, 2011).

Over the time, significant portions of this traditional knowledge were obscured or lost, primarily due to inadequate documentation. While certain remedies can be ascribed to renowned healers, the origins of numerous formulations are ambiguous. Another prominent issue confronting herbal medicine is the challenge of standardization, arising from the intricate phytochemical profiles of (Karbwang *et al*., 2019). This makes achieving uniformity in dosage and therapeutic outcomes difficult. In the absence of stringent quality control mechanisms, the potential for contamination, adulteration, or misidentification of plants increases. Moreover, the empirical validation for numerous herbs is evidently absent, leading to practices more in long-held beliefs rather than demonstrable efficacy.

Rise in Global Demand for Herbal Remedies and the Importance of Ensuring Safety and Efficacy

The global demand for herbal medicine has seen a significant surge in recent years, driven by an increasing consumer preference for natural remedies and a holistic approach to healthcare. According to a report by Grand View Research, the global herbal medicine market size was valued at approximately $92.13 billion in 2020 and is expected to expand at a compound annual growth rate (CAGR) of 8.6per cent from 2021 to 2028 (Complementary and Alternative Medicine Market Report, 2030). Factors such as

Figure 1 Overview of Traditional Medicinal Systems in Asia and Europe



Source: Author's compilation based on various sources.

the growing awareness of the adverse effects of synthetic drugs, combined with the resurgence of traditional and alternative therapies in both developing and developed nations, have played pivotal roles in this growth. Following are the major factors which contribute to this growth *(Chavda et al., 2022; Pan et al.*, 2014; Yuan *et al*., 2016).

- Herbal remedies with their premise rooted in holistic wellness, resonates with individuals seeking a deeper connection with nature and self.
- As debates around the adverse effects of synthetic compounds in medicines grow, the natural label attached to herbal products finds more appeal. This inclination stems from an inherent distrust of chemicals and the potential adverse reactions they might cause, especially with long-term use.
- In regions like Asia and Africa, these remedies symbolize a rich heritage, encapsulating time-honoured wisdom and traditional healing techniques that have withstood the test of time.
- Herbal remedies aren't confined to treating ailments. Their benefits extend to preventive healthcare, skincare, and dietary supplements. The vast array of applications, from rejuvenating teas to topical ointments, has expanded their market reach and acceptance.

In contrast, there are several risks associated with herbal medicines (de Sousa Lima et al., 2020; Kristianto et al., 2022; Zhou et al., 2016.). Some of them are:

- Inconsistency in potency: The standardized (synthetic) pharmaceuticals have better consistency as they result from controlled industrial processes whereas herbal remedies might exhibit varying chemical composition based on factors such as the origin of plant, mineral content of the soil, and climatic conditions. This can influence the potency and unpredictable therapeutic effects of the herbal drug.
- Exposure to contaminants: Herbal treatments may become dangerous if production and processing standards are not strictly followed. Pesticides, hazardous metals, or other harmful adulterants can introduce health risks, negating the intended therapeutic benefits.
- Interference with synthetic drugs: Harmful drug-herb interactions may occur when people use herbal therapies with allopathic medicines. It may either diminish the efficacy of prescribed drugs or exacerbate side effects.
- Overdosage Concerns: Unlike allopathic medicines that come with well-defined dosage guidelines, many herbal preparations lack such parameters. This ambiguity can lead to unintentional overdosing, with consumers mistakenly believing that Natural equates to harmless.

Importance of Standardisation in Herbal Medicine

Standardisation denotes the systematic process of quantifying and ensuring consistent levels of specific active constituents or marker compounds in a herbal product (Folashade et al., 2012). This is achieved through analytical and biological assays ensuring that every batch of a herbal product meets specified criteria, such as containing a defined quantity of an active compound, and is devoid of contaminants like heavy metals, or harmful microbes.

In the realm of allopathic medicine, active compounds are isolated or synthesized in their purest forms, allowing for tight control over variability and

quality which ensures consistent efficacy and safety. However, herbal medicines present a different challenge considering the innate complexities of herbal matrices. Plants produce a myriad of secondary metabolites such as alkaloids, flavonoids, and terpenoids whose concentrations can vary due to numerous environmental and genetic factors (Roy et al., 2022). For instance, the alkaloid content in a plant might differ based on its growth phase, or the flavonoid profile might alter due to variations in soil nutrient composition (Dias et al., 2021).

Further, therapeutic efficacy might not just depend on one isolated compound, but rather a synergistic interaction of multiple constituents presents in the herbal preparation. This synergy underscores the need for a holistic approach to standardisation, where the entire phytochemical profile is considered rather than isolated components.

Moreover, the post-harvest processing of herbal raw materials, such as drying, grinding, and extraction, can introduce another layer of variability (Lazarjani et al., 2021; Ubeed et al., 2022). Each of these steps can impact the concentration and stability of the active compounds, hence the need to standardise and validate each step.

There may be several implications or side-effects of non-standardized herbal products such as:

Safety: Herbal products can contain harmful contaminants, such as pesticides, heavy metals, and microorganisms. Safety concerns can result from poor practices and lack of knowledge, but sometimes also due to deliberate acts to increase profits. There have been instances of toxic plant substitution due to misidentification. For instance, Belgian slimming pill tragedy in the 1990s, highlighted the dangers of substituting herbs with nefarious counterparts, causing severe kidney injuries (RxISK, 2015) . Some traders also employ pharmaceutical adulterants, where herbal products, marketed as natural have been found laced with pharmaceutical drugs, leading to unintended side effects.

Efficacy: Active content of herbal products varies on several factors, as mentioned above. Such inconsistencies can lead to overdosing or underdosing, compromising therapeutic outcomes. Standardization and quality control can help to ensure that herbal products contain a consistent amount of active ingredients, which is necessary for efficacy.

Therefore, standardisation ensures that herbal medicines despite their inherent complexities, are produced with consistent quality, potency, and safety. This would allow herbal medicines to be integrated into modern healthcare systems with the same rigor and scrutiny as allopathic drugs.

Variability factors at play in Herbal Medicine

Herbal medicines are made from whole plants or plant extracts, which contain a complex mixture of different compounds. The chemical composition of herbal preparations can vary significantly depending on numerous factors: the region where they were grown, the season of harvest, and even between individual plants within the same species (Lavrinenko et al., 2021). Furthermore, once harvested, the potency and safety of these herbs can be compromised by storage conditions, contamination, microbial action. In addition to inherent variability, herbal medicines are susceptible to external factors that can alter the concentration of active compounds.

Regional differences in Plant growth - Environmental factors:

Plants are sensitive indicators of their environment, often revealing subtle shifts in their biochemistry in response to their surroundings. Herb grown in mountains might possess a different biochemical profile than its counterpart cultivated in plains. Temperature, precipitation patterns, humidity, soil, pH, nutrient content, and microbial community can significantly influence a plant's phytochemical composition (Tan et al., 2020; Yang et al., 2022). For instance, ginseng grown in Korea can exhibit different ginsenoside profiles compared to that grown in China, largely attributable to diverse environmental conditions (Chen et al., 2019).

Seasonal variations - Harvesting and processing methods:

The temporal dimension of harvesting is crucial for many plants. A plant accumulates its active compounds seasonally. Harvesting at the wrong time might yield a less potent medicine. Also, drying, storage and processing of plant material can impact its medicinal properties. Some plants, when dried under direct sunlight, might lose essential volatile compounds, while others might require specific temperatures to retain their potency. For instance, Hypericin content in *Hypericum perforatum*, renowned for its potential as a natural antidepressant can vary substantially depending on the region in which the plant is grown and the time of harvest (Southwell & Bourke, 2001).

Differences within the same species - Botanical factors:

There can be vast differences between varieties and cultivars within a single species. Moreover, the specific part of the plant; root, leaf, stem, or flower vary in its chemical composition. Lavender, for instance, has multiple species and varieties, each with its unique aromatic profile and therapeutic attributes (Habán et al., 2023).

Post-harvest challenges:

Once harvested, the plant material faces a set of challenges that can modify its composition. Exposure to oxygen can lead to oxidative degradation of certain compounds. Improper handling can introduce contaminants or lead to the growth of mould and fungi, potentially producing mycotoxins that are harmful when ingested.

Storage conditions:

Storage conditions, including temperature, humidity, and exposure to light, can degrade the potency of herbal products over time due to alteration the phytochemistry of stored plant material. For instance, certain flavonoids in stored plant materials can degrade or transform when exposed to high temperatures or excessive moisture (Luisa et al., 2020).

Contamination risks:

Herbal medicines, especially when sourced from multiple regions, run the risk of contamination. From pesticides used during cultivation to heavy metals absorbed from the soil or introduced during processing, these contaminants can pose significant health risks.

Microbial action:

Microbial activity on herbal medicines can result in the degradation of active compounds and the production of metabolites that may not have been present initially. Some microbes can also produce secondary metabolites with potential

health implications. For instance, certain fungi can produce aflatoxins, potent carcinogens, when growing on improperly stored plant materials (Klich, 2007).

Quality Assurance of Herbal Raw Materials and their Products

Apart from the inherent variability of chemical composition, the medicinal plants growing in nature may also be exposed to various toxins / impurities present in the environment such as heavy metals (lead, inorganic arsenic, cadmium, and mercury), microbial contamination, fungal contamination like Aflatoxin and pesticide residues (Brima, 2017). These contaminants along with the storage conditions and processing methods may affect the quality and efficacy of the herbal medicinal product made from these herbal raw materials and may result in harmful effects. For example, presence of arsenic in herbal products beyond permissible levels, can pose serious health hazards.

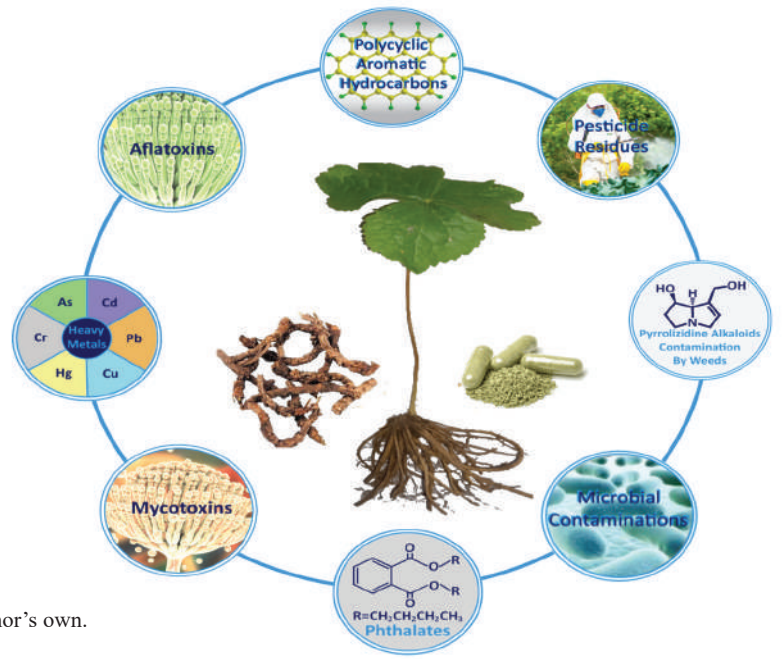
One important aspect of quality control measures is botanical authentication and identification, are essential to confirm that the herbal material used is the correct species and is free from adulteration. This is crucial for maintaining the integrity of herbal products.

Rigorous quality control testing, employing techniques like atomic absorption spectroscopy and polymerase chain reaction (PCR), is indispensable to mitigate these risks and safeguard public health.

Figure: Potential environmental contaminations affecting herbal raw material and their products.

To ensure safety and quality of herbal medicinal products, the herbal raw materials should be subjected to various quality checks as given below:

Figure 2: Potential Environmental Contaminations Affecting Herbal Raw Material and their Products



Source: Author's own.

Macro and microscopic examination:

Quality control of herbal drugs requires analysis at different level to check for adulterants or foreign matter. Macroscopic and microscopic examination is employed to determine the presence of foreign matter such as chemical residue or microbial contaminants which can be determined by techniques like chromatography, spectroscopy, or microscopy (Bandaranayake, 2006).

Chemical Fingerprinting/Quantitative determination of active constituent(s):

Active ingredient of the herbal plant extract can be evaluated by various technique such as HPLC/ GC to determine pharmacological activity, potency, and toxicity. This also provides valuable additional information on the identity/ authenticity of the herbal raw material (Jha, 2020).

Determination of moisture content:

Moisture content in herbal raw material is a significant quality parameter. Moisture level of 5–10per cent is normally present in all dried drugs, but an excess of moisture is considered as an adulterant. In rhizome, roots and stolons, the water content should not be more than 12per cent.

Determination of Microbial Contaminants and Aflatoxins:

Herbal plants are associated with various microbial contaminants, represented by bacteria, fungi, and viruses often originating in the soil. Poor methods of harvesting, cleaning, drying, handling, and storage can cause additional contamination.

The presence of fungi and aflatoxins should be carefully investigated (Kutasi et al., 2021). Techniques for the determination of aflatoxin contamination in herbal drugs are published by the WHO.

Total Phenolic and Flavonoid content:

Measures the total amount of phenolic and flavonoid compounds, which contribute to the antioxidant properties of the herbal product.

Determination of essential oils:

Quality and quantity of essential oils obtained from the herbal preparations can be determined by methods such as TLC, HPLC, GC, quantitative TLC (QTLC), and high-performance TLC (HPTLC). New techniques such as Over-pressured layer chromatography (OPLC), infrared and UV-VIS spectrometry, MS, GC/MS, LC/MS, and MS/MS, and nuclear magnetic resonance (NMR) are powerful tools for standardization and to control the quality of the raw material and the finished product.

The results from these sophisticated techniques are used in quality control of herbal products as they provide a chemical fingerprint to determine the nature of chemicals or impurities present in the herbal raw material or extract.

Tests for heavy metals:

Medicinal herbs can be contaminated by heavy metals can attribute to cause clinically relevant dangers for the health of the user and should therefore be limited. Allowed permissible limit of heavy metals can be found in Indian pharmacopoeias and can be experimentally confirmed with reagents such as thioacetamide or di-ethyl dithiocarbonate (Indian Pharmacopoeia, Volume 1, 2007).

Determination of pesticide residues:

Herbal raw materials may contain

pesticides and fumigants at unsafe level which may be toxic when prepared into herbal drugs. Therefore, concentration of pesticide residue should be checked in the raw herbal material prior to its processing.

Quality control measures in herbal medicine encompass a series of systematic and rigorous procedures designed to ensure the safety, efficacy, and consistency of herbal products (Muyumba et al., 2021). These measures are essential to meet regulatory standards, protect consumer health, and support evidence-based practice. Here are various quality control measures commonly employed in the herbal medicine industry:

- Accelerated aging studies: Evaluates the stability of the product over time by subjecting it to various environmental conditions to assess shelf life and storage recommendations.
- Development of reference materials: Establishes reference standards for herbal materials and compounds to serve as benchmarks for quality and consistency.
- Comparative testing: Compares the herbal product against established reference materials to verify its authenticity and quality.
- Label compliance: Ensures that product labels accurately reflect the contents of the product and dosage recommendations in compliance with regulatory requirements.
- Documentation and record keeping: Maintains comprehensive records of manufacturing processes, quality control tests, and batch records.
- Adherence to GMP guidelines: Enforces adherence to Good Manufacturing Practices to ensure consistent quality throughout the production process.
- Quality Assurance and management systems: Establishes and maintains quality management systems to continuously monitor and improve product quality.
- Regulatory review: Ensures that the herbal product complies with local, national, and international regulatory standards and requirements.
- Independent laboratory testing**:** Some manufacturers opt for third-party testing by accredited laboratories to verify the quality and safety of their herbal products.

Implementing these quality control measures is crucial for herbal medicine manufacturers to produce safe, effective, and consistent products. These measures not only benefit manufacturers by ensuring regulatory compliance and consumer trust but also protect the health and well-being of consumers who rely on herbal remedies.

Standardization of Herbal Medicine Formulations

Safety is one of the most important reasons for the necessity for standardisation in herbal medicine. The content of herbal formulations can vary greatly depending on plant species, growth conditions, and processing processes. There is a possibility of contamination, adulteration, or the existence of harmful compound. Standardisation establishes stringent quality guidelines that ensure herbal goods satisfy safety standards and are free of dangerous toxins.

The efficacy of herbal medicine is closely tied to the presence and concentration of active compounds. Standardization involves identifying and quantifying these bioactive constituents, ensuring that each batch of herbal medicine maintains consistent potency. It entails the identification and quantification of active constituents, setting acceptable limits for contaminants, and implementing

consistent manufacturing processes. For example, standardized extracts of *Ginkgo biloba*, a widely used herb for cognitive enhancement, specify the minimum content of active compounds known as ginkgolides and bilobalide (Shareena et al., 2022). Standardization in herbal medicine involves ensuring uniformity in the composition and quality of herbal products. This consistency is crucial for achieving reliable therapeutic outcomes, whether in clinical practice or scientific research.

To address these issues, ongoing research is focused on developing innovative techniques for standardization and quality control. Metabolomics, spectroscopy, and chemometrics are emerging as promising tools for characterizing herbal products more comprehensively.

In the pursuit of enhancing standardization and quality control in herbal medicine, several innovative technologies have gained prominence. These technologies not only offer greater precision but also expedite the analysis of herbal products, further reinforcing the importance of staying at the forefront of scientific advancement (Bansal et al., 2013).

- **Metabolomics** is a cutting-edge approach that involves the comprehensive analysis of all small molecules (metabolites) present in a biological sample. In the context of herbal medicine, metabolomics can provide insights into the intricate chemical profiles of herbal preparations. By identifying and quantifying a wide range of metabolites, researchers can gain a deeper understanding of the pharmacological effects and safety profiles of herbal remedies.
- **Spectroscopic** techniques, including nuclear magnetic resonance (NMR) spectroscopy and infrared (IR) spectroscopy, have gained traction in herbal medicine analysis. These methods offer rapid and non-destructive means of characterizing the chemical composition of herbal products. With advances in instrumentation and data analysis, spectroscopy is becoming increasingly valuable for quality control purposes.
- **Chemometrics** is a multidisciplinary field that leverages advanced statistical and mathematical techniques to interpret complex chemical data. In herbal medicine, chemometrics can help researchers identify patterns, correlations, and outliers in large datasets. This aids in quality control by enabling the detection of irregularities or adulteration in herbal products.

Thus, there are immense benefits of standardization and quality control such as: enhanced consumer trust and confidence, consistent therapeutic outcomes, reduction in adverse effects and health risks and facilitating regulatory approvals and global trade.

Success Stories Showcasing the Benefits of Strict Standardization and Quality Control

Rigorous standardization and quality control in the realm of herbal medicine have yielded numerous success stories, showcasing improved safety, efficacy, and trustworthiness of these natural products. For instance, Artemisinin, derived from *Artemisia annua* has become a cornerstone in the treatment of malaria. Rigorous standardization has enabled the consistent production of artemisinin combination therapies (ACTs), which are endorsed by the World Health Organization and have saved countless lives (Davis et al.,

2005). Similarly, the use of willow bark dates to ancient civilizations for pain and fever relief. Modern quality control and standardization led to the isolation of salicin from willow bark, eventually paving the way for the synthesis of aspirin which is one of the world's most widely used medications (Desborough & Keeling, 2017).Digitalis which is derived from the foxglove plant has been used to treat heart conditions. Standardization and rigorous testing have transformed this herbal remedy into prescribed drugs (digoxin) with known dosages and efficacy (Gheorghiade et al., 2006). Roots of *Valerian* have sedative properties. With proper standardization, products containing *Valerian* offer a natural alternative or complement to synthetic sleep aids, with consistent potency ensuring its safety and efficacy (Guadagna et al., 2020). Most commonly, turmeric and its active component, curcumin, have gained global recognition for anti-inflammatory properties (Sharifi-Rad et al., 2020). Standardization ensures that supplements contain a precise and effective dose of curcumin allowing for reproducible health benefits.

These examples demonstrate the benefits of combining ancient herbal wisdom with modern scientific precision. Herbal medicines can attain their full potential when suitable standardisation and quality control methods are implemented, providing safe and effective solutions to a wide range of health concerns.

Recommendations for Stakeholders

The future of herbal medicine standardization and quality control holds exciting possibilities. As technology continues to evolve, it is likely that even more sophisticated analytical tools will emerge. While embracing the holistic and natural attractiveness of the herbal treatments, stakeholders must improve various practices thorough research, standardisation, and quality control, from manufacturers to consumers. Collaborative efforts among researchers, herbal product manufacturers, regulatory agencies, and traditional medicine practitioners are vital. These partnerships can lead to the development of standardized testing protocols, establishment of reference materials, and sharing of knowledge to advance the field collectively.

Policymakers

The growth and increasing acceptance of herbal medicines worldwide have necessitated robust regulatory frameworks to ensure safety, efficacy, and consistent quality of these products. Policymakers play a crucial role in shaping this landscape, and their proactive involvement can catalyse meaningful advancements in this sector:

- Harmonizing Global Regulations: Depending on the legislation governing foods and medicines, different countries have distinct definitions and classifications for herbal drugs. In different nations, a single medicinal plant may be classified as a food, a dietary supplement, or a herbal medicine. This not only muddles the classification of herbal medicines for national drug control purposes, but it also confuses consumers. Harmonised rules are essential since herbal products are traded across international borders. Regulatory organisations can derive best practises, pool resources, and establish complete frameworks that respect both tradition and scientific rigour by collaborating on a worldwide scale.

- Mandating Comprehensive Quality Control: Regulatory authorities must mandate stringent quality control measures, covering every aspect from raw material sourcing, processing, to the final shelf life of the product. This ensures that manufacturers adhere to uniform standards, making products safer and more reliable for consumers.
- Encouraging Research and Development: Policymakers can promote research into safety, efficacy, and standardization of herbal medicine by providing grants, subsidies, or tax benefits. This would not only foster innovation but also provide the scientific evidence required for mainstream acceptance.
- Educating the Public and Health Professionals: Active campaigns, sponsored by regulatory authorities, can heighten public awareness about the advantages of standardized herbal products and the risks associated with sub-standard or adulterated ones. Additionally, training programs for allopathic doctors can be initiated, emphasizing potential interactions between herbal and conventional medicines, thus promoting integrated patient care.
- Developing Pharmacovigilance Systems: Like allopathic medicines, herbal medicines should be subject to post-market surveillance. Policymakers can facilitate the development of systems to report and monitor adverse events related to herbal products, offering insights into real-world safety profiles.
- Strengthening Supply Chain Integrity: As raw materials of herbal medicines predominantly come from natural sources, ensuring sustainable and ethically sound sourcing is crucial (Yuan et al.,2016). Policies can be framed to encourage fair trade practices, sustainable farming, and traceability throughout the supply chain.
- Fostering Public-Private Partnerships: Governments can collaborate with industry stakeholders, traditional practitioners, and academic institutions, creating synergies to address the challenges in herbal medicine standardization and quality control.

Herbal Medicine Manufacturers

Manufacturers play a pivotal role in ensuring that herbal medicines meet the highest standards of safety, quality, and efficacy. By actively adopting and promoting best practices, they can not only win the trust of consumers but also contribute significantly to the broader acceptance and adoption of herbal medicine in mainstream healthcare. Here's how they can make a difference:

- Investing in Research and Development (R&D): Herbal manufacturing companies can allocate resources to study the therapeutic properties, mechanisms, and optimal dosages of herbal ingredients. Such R&D efforts can validate traditional references and identify potential new applications.
- Implementing Rigorous Quality Control Protocols: By establishing stringent in-house quality control measures, manufacturers can guarantee the consistency and purity of their products. This involves monitoring each stage of the production process, from raw material sourcing to finished product testing.
- Adhering to Good Manufacturing Practices (GMP): Compliance with GMP standards ensures that herbal products are manufactured consistently and at a quality level appropriate for

their intended use. It covers various aspects, including hygiene, equipment validation, and employee training.

- Engaging in Sustainable and Ethical Sourcing: Ensuring that raw materials are sourced sustainably and ethically can preserve biodiversity and strengthen the long-term viability of herbal medicine. This involves respecting traditional knowledge, promoting fair trade, and implementing traceability measures.
- Collaborating with Traditional Practitioners: By working with traditional herbal practitioners, manufacturers can tap into centuries-old wisdom. Such collaborations can provide insights into lesser-known herbal remedies, optimal harvesting techniques, and traditional preparation methods.
- Educating Consumers and Healthcare Professionals: Manufacturers can launch educational campaigns highlighting the importance of standardized and quality-controlled herbal products. They may provide clear labelling, detailed product information, and transparency about their manufacturing processes.
- Engaging in Third-party Testing: By subjecting their products to third-party testing, manufacturers can provide an added layer of assurance about product quality and potency. Independent certifications can further boost consumer trust.
- Actively Participating in Regulatory Framework Development: Manufacturers should take an active role in shaping regulations by engaging with policymakers, and standardization bodies.
- Fostering Collaborations with Academia: Partnerships with academic institutions can facilitate advanced research, validation studies, and the development of innovative extraction or formulation technologies.

Researchers and Academicians

There is an acute need to promote further research on herbal formulations. The traditional guidelines related to dosage and indications, vary across various sources. In an era where evidence-based medicine is the gold standard, there is a need to create standard research-based guidelines including well documented dose-response relationships. The traditional medicinal system was devised considering the climate, food, and life-style habits of the people in that period. In the current context of living conditions and habits, some of the formulations may need to be updated.

The integration of traditional medicinal wisdom with contemporary scientific methodologies represents a fusion of centuries-old practices with cutting-edge research, yielding a robust and comprehensive approach to healthcare. This can lead to following benefits:

- Preservation of Traditional Knowledge: Traditional practitioners often possess a wealth of empirical knowledge, passed down through generations, about the use of various herbs, their combinations, and methods of preparation. Collaborating with modern scientists ensures that this knowledge is not only preserved but is also documented and disseminated more widely.
- Scientific Validation: Modern scientific methods can provide the analytical rigor required to validate the efficacy and safety of traditional remedies. Through techniques like randomized clinical trials, bioassays, and molecular studies, the therapeutic claims of

traditional medicines can be scrutinized and verified.

- Optimization of Formulations: With a better understanding of phytochemistry and pharmacology, modern scientists can work with traditional practitioners to refine and optimize herbal formulations, enhancing their potency, reducing side effects, or improving their bioavailability.
- Biodiversity Conservation: Traditional practitioners often have knowledge about local biodiversity and the medicinal properties of endemic plants. Collaborative efforts can lead to conservation initiatives, ensuring that valuable plant species are protected and cultivated sustainably.
- Socio-economic Benefits: Validating and commercializing traditional remedies can have significant economic implications, especially for indigenous communities. It can lead to job creation, sustainable farming practices, and even the development of local enterprises.
- Educational Synergy: Bridging the gap between tradition and modern science can lead to enriched educational programs where students of medicine, both traditional and modern, gain a broader perspective, ensuring the practitioners of tomorrow are well-rounded in their approach.

Conclusion

In conclusion, standardization and quality control are indispensable enablers of herbal medicine research and practice. They ensure the reliability, safety, and efficacy of herbal products, instilling confidence in both consumers and healthcare professionals. As herbal medicine continues to gain popularity globally, ongoing research and advancements in standardization and quality control are essential to meet the growing demand for evidence-based, high-quality herbal therapies. It is also crucial that traditional healers and modern medicine practitioners collaborate, leveraging their expertise. By integrating the wisdom of age-old practices with contemporary research methodologies, they can collectively devise more holistic treatment strategies. Through collective efforts from regulators, manufacturers, and researchers, safer and more effective herbal products can be achieved. The future of herbal medicine lies in a harmonious blend of tradition and innovation, where standardization and quality control serve as the bridge to a healthier future.

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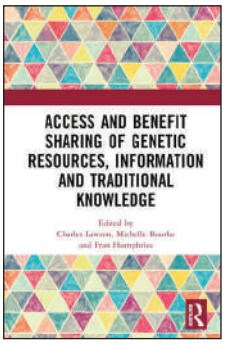
Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge



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The Convention on Biological Diversity (CBD)'s objectives of biodiversity conservation, sustainable use of its components and the fair and equitable sharing of benefits arising out of the use of genetic resources are being attained through the concept of Access and Benefit Sharing (ABS). This is further elaborated in the Nagoya Protocol of 2014. The CBD's bargain was a settlement between governments of the technologically advanced North and the biodiversity rich South which would facilitate transfer of genetic resources from the South to the North in exchange for finances and technology including biotechnology from the North to the South. For contracting parties the CBD imposes obligation to take 'legislative, administrative or policy measures as appropriate' to achieve 'sharing in a fair and equitable way' both the benefits from commercialisation and other utilisation and the results of research and development'. The initial focus on the legal obligations established by the CBD and the form of obligations for collecting physical biological materials have now shifted onto a far more complex series of disputes and challenges about the ways ABS should be implemented and enforced. There remains an increasing concern that the ability to exploit information about biological materials without the actual physical materials will undermine ABS. The Kunming Declaration of 2020 is step towards addressing this lacuna. It is an attempt to 'step

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up efforts' addressing ABS and 'the context of digital sequence information on genetic resources'. The changing developments in the way genetic resources are being shared, the changing nature of exchange of information and the consequent debates on what constitutes 'genetic resources' within the framework of CBD makes a case for reviewing the challenges and opportunities within the context of ABS.

Literature on ABS has been mostly focussing on compliance with regulatory aspects of ABS, the hurdles in scientific research and related social legal and policy debates although this is an evolving field of research and engagement and debates about ABS have moved on. This volume by Charles Lawson, Fran Humpfries and Michelle Rourke attempts to highlight new insights into some of the old problems and new perspectives on currently developing positions of conflict. This book has been divided into four major themes i.e. governance issues, Digital Sequence Information (DSI), rights of indigenous and local communities and compliance measures for the users genetic resources. Any understanding of the ABS of genetic resources and traditional knowledge is incomplete without the above mentioned themes. Theme 1 on Governance issues includes chapters that analyse issues of sovereignty within the CBD, issue of 'common heritage' and WHO's approach to pathogen sharing, issue of ABS within future potential Pandemic Treaty and other international public health agreements, the issue of DNA computers with reference to the underlying assumptions on ABS concept and importantly the status of conservation within the framework of ABS, biodiscovery and biotrade. Theme 2 on Digital Sequencing Information and Dealing with Information looks at basic questions on what we mean by the term 'open access' and whether this term is consistent with ideals of benefit sharing, the current arguments in favour of regulating DSI, sequence data flow in and out of countries, and also contemporary concerns about DSI in regional governance arrangements in Africa. Theme 3 i.e. Embracing Indigenous People and Local Communities makes observations on legal framework for indigenous communities in the Nagoya Protocol. It includes chapters that assess status of traditional knowledge in biocultural protocols in ABS to create a legal space for indigenous people's ABS transactions, region specific biocultural protocols such as those in the Pacific. Finally theme 4 that is on Compliance Measures for Users of Genetic Resources addresses the perennial problem of enforcement. This includes perspectives of countries like USA which is a non-party to CBD/Nagoya Protocol, legalities posed by climate litigation, human rights and indigenous people's intellectual property in the context of the Torres Strait Eight litigation.

The volume aptly brings out the complex web of international agreements that regulate access, transfer and use of genetic resources. Given the uncertainties, the volume stresses on the failure and fault lines within the CBD and Nagoya Protocol throughout. It has been opined that CBD has gone ahead with commodification and financialisation of nature instead of preservation of biodiversity. At the same time argument has also been placed on the logical inconsistency of placing disease causing agents (eg issue of pathogen sharing) to a treaty dealing with biological conservation. Over all an emphasis has been placed on the rights of users of genetic resources and a hence the solutions offered have also been user driven solutions to the presented uncertainties of the Nagoya Protocol by the authors. While arguments which offer a balance in terms mapping developments in building a techno-legal infrastructure to track

bioprospecting activities like in the case of India or the case of biocultural protocols as one of the few legal tools internationally recognised to allow for the community based implementation of ABS provisions and the expression of indigenous and local people's development aspirations, have been placed, the overall focus of the volume has been in revisiting the utility of the ABS regime.

That the CBD and Ngaoya Protocol at the very least have served as a deterrent to unhinged access to genetic resources from the South appears to have been a argument that the authors have moved beyond. It is however acknowledged that the DSI debate on ABS is about interests and values not about objective assessment of the impact sovereign rights over genetic resources and associated information will have on innovation. Thus the global North and its industries are certain that any ABS restrictions on DSI would be detrimental to R&D, although the North is happy to tolerate restrictions other types of genetic information on the basis that will encourage R&D.

The Volume does raise important questions and will be of interest to those interested in understanding the gamut issues that are linked to ABS regime especially in light of emerging global health emergencies, technological developments, R&D on genetic resources and the changing nature of access and compliance with respect to such resources.

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